Chatom Primary Care, P.C. v. Merck & Co., Inc.

RESPONSE in Opposition re MOTION to Dismiss Plaintiffs' Amended Complaint

E.D. Pa. January 11, 2013

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: MERCK MUMPS VACCINE ANTITRUST LITIGATION	Master File No. 2:12-cv-03555 ORAL ARGUMENT REQUESTED
THIS DOCUMENT RELATES TO: ALL ACTIONS	

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO MERCK & CO., INC.'S MOTION TO DISMISS PLAINTIFFS' CONSOLIDATED AMENDED COMPLAINT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

RULES & STATUTES

OTHER AUTHORITIES

MISCELLANEOUS

PRELIMINARY STATEMENT

Plaintiffs, Andrew Klein, M.D., John I. Sutter, M.D., and Chatom Primary Care, P.C. ("Plaintiffs"), respectfully submit this Memorandum of Law in Opposition to Merck & Co., Inc.'s ("Merck") Motion to Dismiss the operative Complaint in this action.

This case is about Merck's total dominance and 100% control of the U.S. Market for Mumps Vaccine[1] (the "Relevant Market"). Merck does not wield this monopoly power through the development of a superior product or due to its business acumen, but through a decade-long campaign of lies and deceit regarding the efficacy of its Mumps Vaccine. After two unprecedented mumps outbreaks, the public is only now discovering that Merck's vaccine is *not* as effective as claimed. Merck has known for years that it could not possibly deliver on its claim of at least 95% efficacy. Instead of disclosing the failings of its vaccine – and spurring the inevitable development of superior alternatives by competitors – Merck protected its monopoly by willfully concealing the truth about the diminished efficacy of its Mumps Vaccine in product labeling, marketing materials and public statements during recent mumps outbreaks. Merck even went so far as to falsely declare that "[it has] absolutely no information to suggest that there is any problem with the vaccine." (Consolidated Amended Complaint ("CAC" or "Complaint") ¶ 100). U.S. government agencies have, by now, lost faith in Merck's representations regarding the efficacy of its vaccine. The U.S. Food and Drug Administration ("FDA") is currently examining the vaccine's effectiveness because recent mumps outbreaks "indicat[e] lower vaccine efficacy than previously estimated,"[2] and the National Institutes of Health ("NIH") is now

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[1] As used herein, the term "Mumps Vaccine" includes Merck's M-M-R®II and ProQuad® vaccines.

[2] Steven Rubin, Ph.D., *Determining the Safety and Efficacy of Vaccines to Protect Against Viruses that Infect the Central Nervous System*,

(continued)

funding the development of a new vaccine because the recent outbreaks "strongly suggest that the current vaccine is not effective." (CAC ¶ 117).

This case is not about conjecture or speculation. As set forth in Plaintiffs' well-pleaded Complaint, the facts underlying this lawsuit come from the eyewitness accounts of not one, but two former Merck virologists who witnessed firsthand the desperate measures Merck was willing to take to conceal the diminished efficacy of its Mumps Vaccine. These measures, which included manipulating test data, falsifying test results, intimidating employees and destroying evidence, were all admittedly undertaken by Merck as a "business decision" to maintain its exclusive license to sell Mumps Vaccine in the U.S. (CAC ¶ 70).

As Merck would have it, even accepting these well-pleaded allegations as true (as this Court must do on a motion to dismiss), Plaintiffs fail to articulate any legally cognizable claim. As set forth below, each of Merck's arguments should be rejected out of hand as an unwarranted attempt to limit the application of federal antitrust law, as well as certain state law and common law remedies. Thus, Plaintiffs' claims for monopolization in violation of Section 2 of the Sherman Act, violations of state consumer protection laws, breach of contract, breach of Pennsylvania's express and implied warranty laws, and unjust enrichment should be allowed to proceed.

STATEMENT OF FACTS

Merck originally obtained government approval to sell its Mumps Vaccine in 1967. (CAC ¶ 24). At the time, Merck conducted field studies to determine that the vaccine had an

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http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/BiologicsResearchAreas/ucm127315.htm (last updated Nov. 11, 2011).

efficacy rate of 95% or higher, *i.e.*, 95% of those given the vaccine were considered immunized against mumps. (CAC ¶¶ 34). Because of the manner by which Merck creates its Mumps Vaccine, the efficacy of the vaccine has significantly diminished over the past forty-five years. (CAC ¶ 5). The foundation of Merck's Mumps Vaccine is an attenuated virus – a virus unable to replicate enough in a patient to cause illness, but still able to invoke an immune response capable of protecting against future infection – which is created by "passaging" the virus through a series of cell cultures or animal embryos. (CAC ¶ 5). Over time, Merck's continued passaging of the attenuated virus, from which its original Mumps Vaccine was created, has altered the virus and degraded the vaccine's efficacy. (CAC ¶ 6).

Merck's campaign of deception began in the late 1990s. After it initiated new efficacy testing of its Mumps Vaccine, Merck found that initial testing methodologies could not replicate the 95% efficacy rate achieved back in 1967. (CAC ¶¶ 7-9, 38-53). Merck then resorted to falsifying test data to obtain the desired efficacy. (CAC ¶¶ 9, 54-63, 65). Merck covered up its fraudulent testing by destroying evidence, lying to the FDA, offering financial incentives to cooperative employees and threatening Stephen Krahling,[3] a virologist in Merck's Vaccine division at the time, with incarceration if he reported the fraud. (CAC ¶¶ 10, 62, 67-69, 71-75).

Despite knowing full well that its Mumps Vaccine had significantly diminished in efficacy, over the next decade Merck continued to promote and market the vaccine as having an efficacy rate of at least 95%. Merck not only misrepresented and concealed the true efficacy of its vaccine on its package insert and labeling (CAC ¶¶ 84-86), but also in applications submitted to the FDA and the European Medicines Agency ("EMA") for approval of the vaccine (CAC ¶¶

[3] Mr. Krahling is a relator in the related *qui tam* action, *United States ex rel. Krahling v. Merck & Co., Inc.*, No. 10-cv-04374-CDJ (E.D. Pa.).

87-91), and in an application for a labeling change as to the potency of its M-M-R®II vaccine (CAC ¶¶ 92-94). Moreover, during the unprecedented mumps outbreaks in 2006 and 2009, Merck failed to inform the U.S. government or public of its knowledge of the vaccine's diminished efficacy, instead declaring that it had no reason to believe there was a problem with the vaccine. (CAC ¶¶ 95-110).

As a result of these false representations and omissions regarding its Mumps Vaccine, Merck has been able to unlawfully maintain a monopoly in the U.S. Market for Mumps Vaccine and has foreclosed potential competitors from entering the market for over a decade. The artificially high efficacy bar Merck established through fraud and concealment has discouraged other manufacturers from investing the considerable resources necessary to compete in the U.S. Market for Mumps Vaccine. (CAC ¶ 111). While the NIH funded the development of a new vaccine last year, if the public had known before the historic mumps outbreaks in 2006 and 2009 that Merck's Mumps Vaccine was not as effective as claimed, new vaccines would have likely been developed much earlier. (CAC ¶¶ 114-20).

As a result of its unlawful creation of barriers to entry and exclusion of competition from the market, Merck has been able to charge artificially inflated prices for its Mumps Vaccine. Between December 1999 and April 2012, Merck increased the prices it charged for M-M-R®II vaccine by an astonishing 85%. (CAC ¶ 125). Plaintiffs and members of the proposed Class, who purchased Mumps Vaccine directly from Merck during the past 13 years, have all been forced to pay such artificially inflated prices for Mumps Vaccine because Merck has foreclosed all competition, including price competition. (CAC ¶¶ 12-14, 126, 167, 174-75, 185-86, 195-96).

ARGUMENT

I. The Complaint Satisfies All Applicable Pleading Standards.

To withstand a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief *that is plausible* on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 697 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)) (emphasis added). As Rule 8(a)(2) of the Federal Rules of Civil Procedure provides, a plaintiff must set forth "a short and plain statement of the claim showing that the pleader is entitled to relief." Its purpose is to "'give the defendant fair notice of what the … claim is and the grounds upon which is rests.'" *Twombly*, 550 U.S. at 555 (quoting *Conley v. Gibson*, 335 U.S. 41, 47 (1957)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.[4]

Importantly, "[a]sking for plausible grounds . . . *does not impose a probability requirement* at the pleading stage," *Twombly*, 550 U.S. at 556 (emphasis added), nor does it require "'detailed factual allegations.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly* at 555). Rather, Rule 8 "simply calls for enough fact to raise a reasonable expectation that discovery will reveal

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[4] The Third Circuit does not have an anomolous, "particular formulation" of the plausibility standard, as suggested by Merck. Memorandum of Law in Support of Merck's Motion to Dismiss Plaintiffs' Amended Complaint ("MTD") at 6, (ECF No. 40-1). Moreover, the case relied upon by Merck for this proposition, *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 228 (3d Cir. 2011), is inapposite. *Burtch* involved an analysis of a Section 1 claim, and whether the circumstantial evidence pleaded was sufficient to plausibly infer an agreement among the conspirators, or whether plaintiff had merely pleaded parallel conduct. By contrast, this case presents a Section 2 claim, where the question of parallel conduct and agreements among conspirators are not at issue. More to the point, Plaintiffs' factual allegations regarding Merck's monopoly and violation of various states' laws are not based on circumstantial evidence but, rather, detailed information and direct evidence regarding Merck's anticompetitive conduct.

evidence of illegal[ity]." *Twombly*, 550 U.S. at 556; *see also In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 319 (3d Cir. 2010).

When ruling on a defendant's motion to dismiss, this Court must accept as true all of the well-pleaded factual allegations contained in the complaint. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (citing *Twombly*, 550 U.S. at 555-56); *Phillips v. County of Allegheny*, 515 F.3d. 224, 231 (3d Cir. 2008) ("The Supreme Court also reaffirmed that, on a Rule 12(b)(6) motion, the facts alleged must be taken as true"). Based on Plaintiffs' detailed Complaint, and the reasons set forth herein, Merck's motion to dismiss must be denied.

II. Plaintiffs' Section 2 Claims Are Legally Sufficient.

Liability under Section 2 of the Sherman Act results from "'1) the possession of monopoly power in [a] 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.'" *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306-07 (3d Cir. 2007) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)). The Complaint pleads facts sufficient to show that Merck possesses monopoly power in the relevant market,[5] and that Merck willfully maintained that power not through the development of a superior product, but by exclusionary, anticompetitive acts, including concealing and misrepresenting the diminished efficacy of its Mumps Vaccine.

"A monopolist willfully acquires or maintains monopoly power when it competes on some basis other than the merits." *LePage's Inc. v. 3M*, 324 F.3d 141, 147 (3d Cir. 2003) (*en banc*). Plaintiffs allege that Merck willfully and illegally maintained monopoly power in the

[5] Merck does not contest that Plaintiffs have pleaded adequate product and geographic markets and Merck's power in those markets.

U.S. Market for Mumps Vaccine by, among other acts, misrepresenting and concealing the true efficacy of its vaccine on its package inserts and labeling (CAC ¶¶ 84-86); in applications submitted to the FDA and the EMA for approval of the vaccine (CAC ¶¶ 87-91); in an application for a labeling change on the potency of its M-M-R®II vaccine (CAC ¶¶ 92-94); and during two recent, unprecedented mumps outbreaks when it declared the vaccine worked just fine. (CAC ¶¶ 95-110). Moreover, as the historic 2006 and 2009 mumps outbreaks among highly vaccinated populations demonstrate, Merck did not maintain its monopoly through "superior product, business acumen, or historic accident," *Grinnell*, 384 U.S. at 570-71, nor competition "on the merits," *LePage's*, 324 F.3d at 147, but rather through willful and anticompetitive deceit. Based on Plaintiffs' well-pleaded allegations, Plaintiffs have satisfied the requirements of a Section 2 claim.

A. Plaintiffs Have Sufficiently Alleged The Type Of Exclusionary Conduct Prohibited By The Sherman Act.

Despite Plaintiffs' detailed Complaint, Merck argues that the Sherman Act condemns only certain types of willful conduct. Merck asserts that a widespread, long-running campaign of misrepresentation and concealment, which created barriers to entry and foreclosed competition, does not fit within its narrow (and self-serving) definition of anticompetitive behavior prohibited by the antitrust laws. To the contrary, however, Supreme Court and Third Circuit precedent, as well as the legislative purpose of the Sherman Act, make abundantly clear that there is no finite list of conduct that violates the antitrust laws.

1. Deception Is A Form Of Exclusionary Conduct That Violates The Antitrust Laws.

(a) The Sherman Act's Legislative History Shows That A Main Purpose Of The Act Is To Prohibit A Monopolist's Deception.

When the Sherman Act was enacted "unfair competition" under the common law was grounded in preventing injury to a competitor through misrepresentation. *See Klingel's Pharmacy of Baltimore City v. Sharp & Dohme*, 64 A. 1029, 1030 (Md. 1906) ("[A]n action will lie for a combination or conspiracy by fraudulent and malicious acts to drive a trader out of business, resulting in damage.") (citing *Van Horn v. Van Horn*, 20 A. 485, 486 (N.J. 1890)); *Messerole v. Tynberg*, 36 How. Pr. 14 (N.Y.C.P. Special Term 1868) ("The market is closed against no one who, in a fair and honest spirit of rivalry, seeks to monopolize the entire trade . . . but the elements of fraud, deceit or malappropriation of another's rights can receive no countenance from courts of equitable jurisdiction."). The Sherman Act's legislative history manifests a clear intent to incorporate the prevailing common law on unfair competition – common law that condemned deception in the marketplace.[6] The Supreme Court has repeatedly said that the federal antitrust laws are the federal common law on unfair competition.[7]

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[6] As Senator Hoar explained at the time, Section 2 of the Sherman Act sought "to extend the common-law principles, which protected fair competition in trade in old times in England, to international and interstate commerce in the United States." 21 CONG. REC. 1351, 3152 (1890).

[7] *See Standard Oil Co. v. United States*, 221 U.S. 1, 60 (1911) ("[T]he standard of reason which had been applied at the common law and in this country in dealing with subjects of the character embraced by the [Sherman Act] was intended to be the measure used for the purpose of determining whether, in a given case, a particular act had or had not brought about the wrong against which the statute provided."); *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 899 (2007) (stating that from its inception, the Sherman Act was treated "as a common-law statute"); *State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997) (noting that it is the accepted "view that Congress expected the courts to give shape to the statute's broad mandate by drawing on common-law tradition") (quotation marks and citation omitted).

(b) There is No Finite List of Conduct that Violates the Sherman Act.

Merck incorrectly argues that there are only eight "[r]ecognized forms of exclusionary conduct sufficient to sustain a claim for monopolization" and that anticompetitive and exclusionary acts of deception are not among them. (MTD at 9-10). Merck's myopic construction of the Sherman Act is squarely refuted by the Third Circuit, which makes clear that "[a]nticompetitive conduct can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties." *LePage's*, 324 F.3d at 152 (internal quotation marks omitted). "[A] monopolist is not free to take certain actions that a company in a competitive (or even oligopolistic) market may take, because there is no market constraint on a monopolist's behavior." *Id.* at 151-52. Indeed, adopting Merck's self-serving interpretation of the Sherman Act would effectively eviscerate a large portion of the antitrust laws.

The breadth of conduct subject to antitrust scrutiny was addressed by the Third Circuit in *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3d Cir. 2007). In that case, Qualcomm held a patent for technology adopted in industry-wide standards necessary to ensure interoperability among cell phone equipment. The standard-setting organization ("SSO") tasked with selecting which technology would go into the standards chose to include Qualcomm's technology only after Qualcomm committed to license its technology to competitors on fair, reasonable and non-discriminatory ("FRAND") terms. *See id.* at 304. Broadcom alleged that Qualcomm deceived the SSO and, in so doing, violated the antitrust laws, when it failed to live up to its promise to license the technology on FRAND terms. *See id.* In considering whether Qualcomm's alleged deception amounted to an antitrust violation, the Third Circuit noted that a patent holder who deceives an SSO regarding the cost or performance characteristics of its technology can obtain

an unfair advantage and obscure the relative merits of alternatives. *See id.* at 313. Thus, the Court held that where a patent holder intentionally and falsely agrees to license essential technology on FRAND terms, and, in so doing, deceives an SSO into incorporating the technology in a standard, the patent holder's subsequent breach of that promise constitutes an anticompetitive act under the federal antitrust laws. *See id.* at 314.

Merck's conduct is analogous to what was found sufficient to state a Section 2 claim in *Broadcom*. Here, Merck engaged in unlawful exclusionary conduct when it maintained its exclusive license to sell Mumps Vaccine in the U.S. Market by concealing the diminished efficacy of the vaccine. Despite its ongoing and continuous duty to provide the FDA with accurate information on the efficacy of its Mumps Vaccine,[8] Merck created significant barriers to entering the U.S. Market by falsely representing an artificial efficacy rate and failing to disclose what it knew about the Mumps Vaccine's diminished efficacy to the FDA. Competitors, customers and regulators believed Merck's lies in continuing to allow Merck, via its exclusive license, to be the sole provider of Mumps Vaccine in the U.S Market. As in *Broadcom*, Merck's deceptive conduct and breach of its duty – here, to provide accurate information to the FDA and the public – constitutes an anticompetitive act in violation of Section 2 of the Sherman Act. The anticompetitive nature of Merck's deceit is only underscored by the admission of one of its employees, who explained that concealing the diminished efficacy of the vaccine was done as a "business decision" (CAC ¶ 70) to maintain and continue Merck's total monopoly in the market. *See Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 500 (1988) ("[U]nethical

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[8] *See* Relators' Memorandum in Opposition to Merck's Motion to Dismiss ("Relators' Opposition) at 10, *United States ex rel. Krahling v. Merck & Co., Inc.*, No. 10-cv-04374-CDJ (E.D.Pa. Oct. 9, 2012), ECF No. 47.

and deceptive practices can constitute abuses of administrative or judicial processes that may result in antitrust violations.").

The *Broadcom* decision readily comports with Supreme Court precedent and numerous cases holding that the enforcement of a legal monopoly provided by a patent or agency approval procured through fraud may violate Section 2. *See, e.g.*, *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 174 (1965); *see also Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240, 1261 (9th Cir. 1982) (holding "the fraudulent furnishing of false information to an agency in connection with an adjudicatory proceeding can be the basis for antitrust liability"); *Israel v. Baxter Labs., Inc.*, 466 F.2d 272, 278-79 (D.C. Cir. 1972) ("No actions which impair the fair and impartial functioning of an administrative agency should be able to hide behind the cloak of an antitrust exemption.").

District courts in the Third Circuit likewise condemn anticompetitive deception. In *Caldon, Inc. v. Advanced Measurement & Analysis Grp., Inc.*, a manufacturer of ultrasonic flow meters for nuclear power plants sued competitors who misstated the accuracy of their own meters to customers and potential customers. 515 F. Supp. 2d 565, 571 (W.D. Pa. 2007). In denying defendants' motion to dismiss, the court clearly stated that the question before it was whether defendants "misrepresented the accuracy of [defendants' product] and disparaged Plaintiff's device so as to violate the . . . Sherman Act[]." *Id.* at 573-74.[9] Like the defendants in

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[9] Courts across the nation similarly hold that deception may be an anticompetitive, exclusionary act in violation of the Sherman Act. *See, e.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34, 76-77 (D.C. Cir. 2001) (holding Microsoft's campaign to deceive developers constituted exclusionary conduct in violation of § 2 of the Sherman Act); *Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C.Cir. 1998) (reversing in part the district court's dismissal of a complaint and holding that radio station's claim that defendants misrepresented the reach of their broadcasting network to advertisers and the government in order to protect its monopoly stated § 2 claim); *Int'l Travel Arrangers, Inc. v. W.*

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Caldon, Merck knew that its product did not live up to its expectations, but it took great efforts to conceal this information from the public to preserve and maintain its monopoly. (CAC ¶¶ 83-85, 100, 107).

Government competition authorities are also increasingly concerned about the anticompetitive effects of deception. In December 2009, the U.S. Federal Trade Commission ("FTC") alleged that Intel maintained its dominance in the worldwide microprocessor markets by, among other things, engaging in a decade-long campaign of deceit that included misrepresenting industry benchmarks to favorably reflect the performance of its central processing units relative to competitors' products.[10] Specifically, the benchmarks Intel publicized "were not accurate or realistic measure of typical computer usage or performance." *Intel Complaint*, ¶¶ 65-66. The FTC explained that "Intel's conduct was misleading and had the purpose and effect of harming competition and thus enhancing Intel's monopoly power." *Id.* ¶

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Airlines, Inc., 623 F.2d 1255 (8th Cir. 1980) (upholding treble damages antitrust award against airline with monopoly power after finding sufficient evidence that airline placed false, deceptive and misleading advertisements discouraging public patronage of travel group charters); *Research in Motion Ltd. v. Motorola, Inc.*, 644 F. Supp. 2d 788 (N.D. Tex. 2008) (denying defendant's motion to dismiss and holding defendant's alleged misrepresentation to SSO that it would license standard essential patented technology on FRAND terms constituted anticompetitive conduct); *Davis v. S. Bell Tel. & Tel. Co.*, No. 89-2839-CIV-NESBIT, 1994 WL 912242, at *2, *7, *15 (S.D. Fla. 1994) (denying summary judgment on allegations of deception to maintain monopoly); *Brownlee v. Applied Biosystems, Inc.*, No. C-88-20672-RPA, 1989 WL 53864, at *5-6 (N.D. Cal. Jan. 9, 1989) (denying motion to dismiss complaint alleging defendants' deceit to potential customers as anticompetitive conduct).

[10] *See* Complaint at 3, 10-11, *In re Intel Corp.*, No. 9341 (Dec. 6, 2009), *available at* http://www.ftc.gov/os/adjpro/d9341/091216intelcmpt.pdf (hereinafter *Intel Complaint*). The *Intel Complaint* followed the European Commission imposing a $1.06 billion fine, Intel's $1.25 billion antitrust settlement with a competitor and the State of New York's antitrust complaint. *See* Summary of European Commission Decision of 13 May 2009 Relating to a Proceeding Under Article 82 of the EC Treaty and Article 54 of the EEA Agreement at 13, 17, 2009 O.J. (C 227), *available at* http://eur-lex.europa.u/LexUriServ/LesUri/Serv.do?uri=OJ:c:2009:227:0013:0017:EN:PDF); Arik Hesseldahl, *The Intel-AMD Settlement: A Play-by-Play*, BUS. WK., Nov. 15, 2009, *available at* http//www.businessweek.com/technology/content/nov2009/tc20091115_692400.htm; Complaint at 78, *New York v. Intel Corp.*, No. 09-00827-JJF (D. Del. Nov. 4, 2009), *available at* http://www.ag.ny.gov/sites/default/files/pdfs/bureaus/antitrust/Intel_COMPLAINT.pdf.

71. Intel ultimately entered into a consent decree with the FTC in which it agreed to refrain from engaging in deception.[11] Merck's argument that deception is not recognized as a form of exclusionary conduct is belied by clear precedent in this Circuit and elsewhere condemning the market effects of deceptive behavior as a violation of the antitrust laws.

Merck also attempts to argue that each of its acts, taken in isolation, do not amount to unlawful, exclusionary conduct. To the contrary, when determining antitrust liability based on a collection of factual allegations, "the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's,* 324 F.3d at 162 (citing *Cont'l Ore Co. v. Union Carbide & Carbon Corp.,* 370 U.S. 690, 699 (1962)); *see also City of Anaheim v. S. Cal. Edison Co.,* 955 F.2d 1373, 1376 (9th Cir.1992) ("[I]t would not be proper to focus on specific individual acts of an accused monopolist while refusing to consider their overall combined effect. . . . We are dealing with what has been called the 'synergistic effect' of the mixture of the elements."). Thus, it is not only Merck's decade-long campaign of deception, but also its anticompetitive acts to cover up that deception, which include destroying evidence, lying to an FDA official, offering to buy employees' silence, and threatening an employee that wished to disclose the fraud, which should be considered in determining whether Merck unlawfully maintained its monopoly. (*See* CAC ¶¶ 10, 62, 67-69, 71-75).

While Merck relies on *West Penn Allegheny Health System, Inc. v. UPMC*, 627 F.3d 85 (3d Cir. 2010) (MTD at 13) to argue that false statements are only pertinent to an antitrust claim if they disparage a rival, nowhere in the decision does the Court make this sweeping pronouncement. In *West Penn*, Pittsburgh's second-largest hospital system sued the city's

[11] Decision and Order at 13-17, *Intel Corp.*, No. 9341 (Aug. 4, 2010), *available at* http://www.ftc.gov/os/adjpro/d9341/100804inteldo.pdf.

dominant hospital system, UPMC, alleging, among other things, that UPMC attempted to monopolize the market for specialized hospital services. *See id.* In upholding West Penn's claim, the court concluded that UPMC had engaged in anticompetitive conduct including predatory hiring, coercing providers not to refer patients to West Penn and making false statements about West Penn. *See id.* at 109-10. As such, *West Penn* stands simply for the proposition that anticompetitive conduct comes in many forms, including disparagement.[12]

Merck's reliance on *Santana Prods., Inc. v. Bobrick Washroom Equip., Inc.*, 401 F.3d 123 (3d Cir. 2005) (MTD at 11) is similarly unavailing because its analysis is limited to deception in the context of a Section 1 claim. Moreover, *Santana* was expressly criticized by the Third Circuit in *West Penn* as "perhaps [] overly broad" in its assertion that "deception, reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned." *West Penn*, 627 F.3d at 109 n.14 (quoting *Santana*, 401 F.3d at 132). More importantly, the facts alleged in this action are fundamentally at odds with those at issue in *West Penn* and *Santana* because here there is no rival for Merck to disparage, as Merck's deception created insurmountable barriers to entry and led to complete market foreclosure. In essence, Merck is advocating a definition of anticompetitive deception so narrow that it exempts the most effective exclusionary conduct of all.

Stearns Airport Equip. Co. v. FMC Corp., 170 F.3d 518 (5th Cir. 1999) (MTD at 12), also does not salvage Merck's argument because it is factually different from the allegations in this action. *Stearns*, an action involving competitors bidding on contracts to provide airline

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[12] Nor, as Merck argues, does this case parallel *Schachar v. Am. Academy of Opthalmology, Inc.*, 870 F.2d 397 (7th Cir. 1989). (MTD at 14). *Schachar* was not, as Merck claims, a Section 2 case, but a Section 1 case about a trade association's ability to publicize its opinion that a procedure was experimental.

boarding bridges to municipal airports, itself lays out the fundamental difference between those cases and this action. As Merck noted, the *Stearns* court proclaimed "that there could be no exclusion as long as the decision on the choice of supplier remained 'in the hands of the consumer' and rivals were free to promote their own goods." (MTD at 12 (quoting *Stearns*, 170 F.3d at 524)). The Fifth Circuit went on to acknowledge:

> Bribery and threats are not competition on the merits. Several cases have found violations of section 2 when a monopolist engages in what appears to be normal competitive behavior, but has manipulated representatives of the consumer to the point that the integrity of the decisional process has been violated.

Id. at 526. Here, the decision on the choice of supplier was *never* in the hands of Plaintiffs because Merck's conduct foreclosed all rivals. While Merck's bribes and threats were aimed at its employees, they were intended to prevent the public and would-be rivals from discovering information that would have removed the unlawfully created barriers to entry and resulted in the emergence of a more competitive market. There is no question that Merck's enforcement of its Mumps Vaccine license created barriers to entry and lessened competition in the market. Indeed, there was *no* competition in the market.

The fact that other vaccine manufacturers may *now* be attempting to enter the U.S. Mumps Vaccine Market does not, as Merck argues, demonstrate that its misrepresentations and omissions had nothing to do with competitors' decisions not to enter the market. (MTD at 14 n. 10). If anything, these current attempts at entry show that Merck's deceit was effective. It was only after the recent mumps outbreaks revealed that the vaccine was not as effective as Merck fraudulently proclaimed, that other manufacturers applied for FDA approval. Consequently, Plaintiffs and Class Members never had *any* choice among rival suppliers, which *Stearns* makes

clear is necessary to defeat a claim of deception as an exclusionary act in violation of the antitrust laws.[13]

B. Plaintiffs Have Identified Sufficient Antitrust Injury Proximately Caused By Merck And, As Direct Purchasers, Have Standing To Bring Their Antitrust Claims.

1. Plaintiffs Have Identified Sufficient Antitrust Injury Proximately Caused By Merck.

Merck's misrepresentations (and omissions) about the efficacy of its vaccine created barriers to entry by discouraging competitors from entering the market because "it would be economically irrational for a potential competitor to bring a new Mumps Vaccine to the Relevant Market unless it thought it could compete with the safety and efficacy of the existing vaccine." (CAC ¶ 31). Without competition, Merck has been able to "increase[] the prices it charge[s] private health care providers, such as Plaintiffs, for M-M-R®II vaccine by an astounding 85%." (CAC ¶ 125). These artificially inflated prices were the direct and inevitable effect of Merck's anticompetitive, exclusionary conduct to maintain and further its monopoly in the relevant market. Plaintiffs suffered antitrust injury when they paid these artificially inflated prices to purchase the Mumps Vaccine. (CAC ¶ 11).

Merck attempts to distort Plaintiffs' well-pleaded allegations by arguing that their antitrust theory relies on speculation that other companies would have gained FDA approval and entered the U.S. Market if Merck had not misrepresented and concealed the diminished efficacy

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[13] The same reasoning applies with respect to Merck's selective quotes from *Sanderson v. Culligan Int'l Co.*, 415 F.3d 620 (7th Cir. 2005) and *Oce North America, Inc. v. MCS Servs, Inc.*, 795 F. Supp. 2d 337 (D. Md. 2011) (MTD at 9-10). In both cases the courts stated that "[f]alse statements about a rival's goods do not curtail output in either the short or long run. They just set the stage for competition in a different venue: the advertising market." *Sanderson*, 415 F.3d at 623, *Oce,* 795 F. Supp. 2d at 345 (quoting *Sanderson*). Here, there could be no competition in the U.S. Market because Merck's deception before the FDA allowed it to illegally gain a competitive edge – only furthered by its dissemination of misleading materials to the public – that prevented other manufacturers from entering the market at all.

of its Mumps Vaccine. (MTD at 16-17). Merck's incorrect interpretation of proximate causation in antitrust cases is squarely refuted by the Third Circuit as well as other federal courts around the country. As explained by the unanimous D.C. Circuit sitting *en banc* in *United States v. Microsoft Corp.*, "neither plaintiffs nor the court can confidently reconstruct a product's hypothetical technological development in a world absent the defendant's exclusionary conduct." 253 F.3d 34, 79 (D.C. Cir. 2001). To "require that § 2 liability turn on a plaintiff's ability or inability to reconstruct the hypothetical marketplace absent a defendant's anticompetitive conduct would only encourage monopolists to take more and earlier anticompetitive action." *Id.* Rather, an antitrust plaintiff need only show "the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power." *Id.*; *see also* 2 Phillip E. Areeda & Herbert Hovenkamp, ANTITRUST LAW ¶ 338a at 317 (2000) ("[T]o require proof that the illegal conduct was the *exclusive* cause of the plaintiff's injury would effectively deny private remedies, because multiple causes always affect everyone."). As such, the critical question is not what the market *would have* looked like but for defendant's anticompetitive conduct, but rather, what it *could have* looked like. *See Microsoft*, 253 F.3d at 79.

The Third Circuit echoed the *Microsoft* Court's articulation of proximate causation in *Broadcom*. In reversing the dismissal of Broadcom's monopolization claim against Qualcomm, a competitor patent-holder who harmed competition by foreclosing rivals from having their technology adopted by an SSO, the Third Circuit noted the lower court's failure to consider that the SSO "*might have* chosen nonproprietary technologies for inclusion in the standard." 501 F.3d at 305 (emphasis added). The Third Circuit explained that it was reasonable to infer the SSO selected Qualcomm's technology to the detriment of patent-holders competing to have their technology incorporated in the standard particularly because "even if [defendant's] technology

was the only candidate for inclusion in the standard," the SSO would have rejected it absent Qualcomm's promise to license the technology on fair, reasonable and non-discriminatory terms. *Id.* at 316. "Thus, the allegations of the Complaint foreclose[d] the possibility" that the inclusion of Qualcomm's technology in the standard "was inevitable." *Id.*

Similarly, in *In re Wellbutrin SR/Zyban Antitrust Litig.*, Judge Kauffman considered whether a valid antitrust claim could be stated where defendants argued that, regardless of any frivolous patent infringement litigation, the generic companies failed to secure FDA approval. 281 F. Supp. 2d 751 (E.D. Pa. 2003). In denying defendants' motion to dismiss, the court found "[d]efendants' ability to pose a plausible and legally permissible version of events that explains why generic manufacturers of Wellbutrin SR have not yet entered the market" did not compel it to grant their motion, because on "a motion to dismiss, the Court must draw all reasonable inferences in favor of Plaintiffs." *Id.* at 757.[14] Judge Kauffman reasoned that it could be inferred that the "burdensome patent litigation" directed the generic companies' resources away from FDA approval, and that this reallocation of funds resulted in a delay of FDA approval. *Id.*

Here, as in *Microsoft*, *Broadcom* and *Wellbutrin*, Plaintiffs allege that other competitors *could have* attempted to license and sell their Mumps Vaccine in the U.S. Market but for Merck's anticompetitive and exclusionary acts. Or that, if the U.S. government knew the true efficacy of Defendant's Mumps Vaccine it "might not have approved the vaccine at all for sale in

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[14] *See also In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 651-52 (E.D. Mich. 2000) (holding but-for causation is not eliminated "simply because the defendant can conjure up a set of facts, contradicting those alleged in the plaintiff's complaint, but supporting an alternative possible cause for Plaintiffs' injuries that would not offend the antitrust laws."); *Va. Vermiculite, Ltd. v. WR Grace & Co.*, 156 F.3d 535, 540 (4th Cir. 1998) (reversing Rule 12(b)(6) dismissal and holding that defendant was "foreclosed from challenging causation simply on the basis that it could have achieved the same result through lawful means.").

the U.S." (CAC ¶¶ 113, 123, 137). As in *Broadcom*, the allegations of the Complaint demonstrate that Merck's position as the exclusive provider of Mumps Vaccine in the U.S. Market was not *inevitable*. This is more than sufficient because "Plaintiffs need not 'allege (or dispose of) all alternative theories of causation to survive a motion to dismiss.'" *In re Neurontin Antitrust Litig.*, MDL No. 1479, 2009 WL 2751029, at *12 (D.N.J. Aug. 28, 2009) (quoting *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 535 (D.N.J. 2004)).

It is more than reasonable to infer that, if competitors had known that Merck's Mumps Vaccine efficacy had degraded over time, they would have attempted to enter the U.S. Market. This inference is further underscored by the admission of one of Merck's own employees, who explained that Merck falsified test data to misrepresent the efficacy of its Mumps Vaccine as a "business decision" (CAC ¶ 70). In other words, had Merck not lied about the efficacy of its vaccine, others would have entered the U.S. Market and Merck would have lost business. Further, as Merck itself admits, in the wake of the historic and unprecedented mumps outbreaks in 2006 and 2009, new manufacturers are now applying for, and the U.S. government is now funding, the development of a new mumps vaccine.[15] Because Plaintiffs have set forth facts consistent with their allegations – that competitors were foreclosed from entering the market – and on a motion to dismiss "the question is whether the claimant can prove any set of facts consistent with his or her allegations that will entitle him or her to relief, not whether that person will ultimately prevail," Merck's alternate theory of the case is irrelevant at this stage of the

[15] *See supra* page 16 (discussing other vaccine manufacturers' recent attempts to enter the market).

litigation. *Tender Touch Rehab Servs., LLC v. Brighten at Bryn Mawr*, No. Civ.A 11-7016, 2012 WL 993532, at *3 (E.D. Pa. Mar. 23, 2012).[16]

Moreover, Merck's argument that to allege antitrust injury, Plaintiffs must demonstrate that the FDA would have approved potential competitors' vaccines for licensing (MTD at 18), is belied by applicable case law. Where manufacturers of generic products allege antitrust injury in the form of sham litigation or fraud in the procurement of a patent by the brand-name defendant, "[s]everal courts have held that a finding of antitrust injury cannot be tied to the status of FDA approval." *Neurontin*, 2009 WL 2751029, at *12.[17]

2. <u>As Direct Purchasers, Plaintiffs Have Standing To Bring Their Antitrust Claims.</u>

Because Plaintiffs purchased Mumps Vaccine directly from Merck, they are the proper, indeed the only, parties in the chain of distribution with standing to bring these federal antitrust claims. (CAC ¶¶ 12-14). Merck's argument that Plaintiffs likely suffered no damages because they may be reimbursed for vaccines they administer to patients is an impermissible pass-on defense that has been repeatedly rejected under federal case-law. (MTD at 5 n.1, 25 n.16) In *Illinois Brick Co. v. Illinois*, the Supreme Court clearly held that *only* the harmed direct purchaser in the distribution chain "is the party 'injured in his business or property' within the

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[16] The pleading standard on a motion to dismiss requires the court to "accept the truth of all factual allegations in the complaint and must draw all reasonable inferences in favor of the [plaintiff]." *Revell v. Port Auth.*, 598 F.3d 128, 134 (3d Cir. 2010). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556).

[17] *See also Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 544-46 (D.N.J. 2000) (accepting the counterclaimants' contention that they need not demonstrate FDA approval to invoke antitrust standing); *Abbott Labs. v. Mylan Pharm.*, No. 05-6561, 2007 WL 625496, at *4 n. 2 (N.D. Ill. Feb. 23, 2007) (observing that basing antitrust injury on "the status of FDA approval relative to the required timing of the suit" would render such injury "wholly contingent on the vagaries of timing of agency action.") (internal quotation marks and citation omitted).

meaning" of the Clayton Act. 431 U.S. 720, 729 (1977).[18] Because Plaintiffs are the first party in the distribution chain to be subject to and harmed by Merck's anticompetitive monopolization scheme, they are the *only* parties with standing to bring federal antitrust claims for damages.

III. The Federal Food, Drug and Cosmetic Act ("FDCA") Does Not Preempt Plaintiffs' Federal Antitrust And State Law Claims.

Merck's decade-long campaign of deceit to maintain its monopoly in the U.S. Market for Mumps Vaccine involved not only misrepresentations and omissions made to the FDA, and on product inserts, but false statements in publicly disseminated promotional and marketing materials. (CAC ¶¶ 84-110). Merck misconstrues outdated Supreme Court precedent to argue that, because Plaintiffs' claims incorporate allegations that Merck misrepresented the true efficacy of its Mumps Vaccine to the FDA and on the vaccine's label, their claims are preempted. What Merck fails to acknowledge is that its misrepresentations and omissions to the FDA and on product labeling are only part of an overall scheme of deception that harmed health care providers like Plaintiffs, who paid inflated prices for Mumps Vaccines of questionable efficacy.

Merck's failure to comply with its duties of disclosure under the FDCA, while relevant to show how Merck was able to maintain its total monopoly on the Mumps Vaccine market, does not turn this private civil litigation into an FDCA case. As the Supreme Court expressly held in

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[18] *See also Gulfstream III Assocs. Inc. v. Gulfstream Aerospace Corp.*, 995 F.2d 425, 439 (3d Cir. 1993) (holding only the direct purchaser of an aircraft, and not a downstream buyer or assignee, has standing to pursue an antitrust claim); *Link v. Mercedes-Benz of N. Am.*, 788 F.2d 918, 930-31 (3d Cir. 1986) (because appellants did not purchase directly from Mercedes, *Illinois Brick* barred their claims); *Merican, Inc. v. Caterpillar Tractor Co.*, 713 F.2d 958, 966-69 (3d Cir. 1983) (finding indirect purchaser, even if a 'direct target' of an antitrust conspiracy, lacked standing under *Illinois Brick*). These policies accord with the Supreme Court's acknowledgement that the direct-purchaser rule denies "recovery to those indirect purchasers who may have been actually injured by antitrust violations." *Illinois Brick*, 431 U.S. at 746.

Wyeth v. Levin, "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." 555 U.S. 555, 575 (2009).[19] In that case, the Court held that allegations of product mislabeling can support private claims even if a defendant did not violate FDCA labeling requirements because the FDA's requirements merely establish a "floor" that manufacturers must not fall below. *Id.* at 577.[20] Wyeth's even "more fundamental misunderstanding" was the belief that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. *Id.* at 570. "[The manufacturer] is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 570-71. Consequently, even if Merck's label satisfied its obligations to the FDA, which Plaintiffs contend it did not, that is independent of the question of whether the label constitutes an anticompetitive act of deceit actionable under the Sherman Act and state laws.

While *Wyeth* involved state law claims, the same logic has been applied to the federal antitrust laws. Numerous cases hold that where defendants violate the Sherman Act through anticompetitive conduct, including fraud on a government agency, they cannot evade antitrust scrutiny. For example, in *Israel v. Baxter Labs., Inc.*, where plaintiff drug manufacturers alleged that certain competitors conspired to prevent their new drug from being approved by the FDA

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[19] In fact, Merck itself acknowledged the FDA's less than omnipotent role in a recent *amicus* brief: "HHS plays an active role in the research, development, and ongoing monitoring and evaluation of the safety of vaccines, even apart from the [FDA's] rigorous licensing process." *See* Brief of Merck, et al., as *Amici Curiae* Supporting Respondents, *Bruesewitz v. Wyeth, Inc.*, No. 09-152, 2010 WL 3048323, at *5 (July 30, 2010).

[20] *Wyeth* only emphasizes the absurdity of Merck's argument that Plaintiffs' state law claims are preempted by federal law because it would be impossible for Merck to label the vaccine accurately while complying with its FDA obligation to use approved labeling. (MTD p. 20). In *Wyeth*, the Supreme Court held that "absent clear evidence that the FDA would not have approved a change to [Defendant's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." 555 U.S. at 572. Such "clear evidence" is not present here. Moreover, Merck has a continuous and concomitant duty to the FDA to ensure that the contents of its vaccine labels are accurate and up-to-date (Relators' Opposition at 10). *See* note 8, *supra*.

by, among other things, "misrepresenting the safety and efficacy of [plaintiffs' product]," the D.C. Circuit expressly preserved plaintiffs' right to prove their antitrust claims. 466 F.2d 272, 274 (D.C. Cir. 1972). The Court found that plaintiffs alleged that "the real purpose of defendants' joint efforts [before the FDA was] to preclude, not induce fair FDA consideration" of plaintiffs' product. *Id.* at 279. "No actions which impair the fair and impartial functioning of an administrative agency should be able to hide behind the cloak of an antitrust exemption." *Id.* at 278-79.[21]

Merck's reliance on the Supreme Court's holding in *Buckman Co v. Plaintiffs' Legal Committee* (MTD at 16, 20) is unpersuasive, not only in light of *Wyeth*, but because *Buckman* rebuffed a decidedly non-traditional tort cause of action. 531 U.S. 341 (2001). In *Buckman*, the Court considered whether a person injured by an FDA-approved medical device could recover from a contractor involved in securing federal approval by showing that the consultant had deceived the agency. In holding the cause of action preempted by the FDCA, *Buckman* emphasized that ordinary preemption principles were inoperative because, unlike claims based "on traditional state tort law principles," *id.* at 352, and implicating "federalism concerns and the historic primacy of state regulation of matters of health and safety," *id.* at 348 (quotation marks and citation omitted), "[p]olicing fraud against federal agencies is hardly 'a field in which the

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[21] *See also Clipper Exxpress*, 690 F.2d at 1261 ("the fraudulent furnishing of false information to an agency in connection with an adjudicatory proceeding can be the basis for antitrust liability, if the requisite predatory intent is present and the other elements of an antitrust claim are proven."); *Woods Exploration & Producing Co. v. Aluminum Co. of Am.*, 438 F.2d 1286, 1297 (5th Cir. 1977) (summary judgment reversed where oil producers allegedly conspired to report false production data to state agency in order to increase production allowance; regulatory scheme did not sanction defendants' alleged conduct); *Warner-Lambert Co. v. Purepac Pharm. Co.*, No. 99-5948, 2000 WL 34213890 (D.N.J. Dec. 22, 2000) (holding that fraudulent listing in Orange Book is subject to *Walker Process* exception to *Noerr-Pennington* immunity); *Abbott Labs. v. Alra Lab., Inc.*, No. 92 C 5806, 1993 WL 293995 (N.D. Ill. Aug. 4, 1993) (allowing claim of fraud based on allegation that party knowingly filed false listing with the FDA concerning coverage of a patent).

States have traditionally occupied,'" *id.* at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Whereas the duties sued upon in earlier preemption cases were independent of federal statutes, the novel cause of action in *Buckman* owed its "existence" to the FDCA. *Id.* at 353.[22] As the court in *In re DDAVP Indirect Purchaser Antitrust Litigation* explained in holding that plaintiffs' state-law antitrust and consumer protection claims based in defendants' sham citizen petition before the FDA were not preempted in light of *Buckman*:

> [Plaintiffs'] claims make freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements, i.e., anticompetitive conduct designed to maintain a fraudulent monopoly through a knowingly invalid patent – sufficient for these claims not to be preempted. Further, proof of fraud on the FDA is not an element of an antitrust claim. It may be *evidence* of such a claim . . . but it is not an affirmative element that Plaintiffs are required to prove to make out an antitrust claim.

No. 05-cv-2237, 2012 WL 4932158, at *15 (S.D.N.Y. Oct. 17, 2012) (citations and quotation marks omitted).

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[22] *See also Lfaivre v. KV Pharmaceutical Co.*, 636 F.3d 935 (8th Cir. 2011) (FDA's regulatory scheme related to prescription medications did not preempt consumer's putative class action against manufacturer of hypertension medication, alleging breach of implied warranty); *In re Bayer Corp. Combination Aspirin Prods. Marketing and Sales Practice Litig.*, 701 F. Supp. 2d 356 (E.D.N.Y. 2010) (buyers' putative class actions alleging state law false advertising and consumer protection claims against pharmaceutical manufacturer for deceptive advertising including false claims to consumers that FDA had approved defendant's products not preempted by FDCA); *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228 (S.D. Fla. 2007) (FDA's approval of label for cholesterol-lowering drug did not preempt patients' state law false advertising claims); *Brasher v. Sandoz Pharms. Corp.*, Nos. CV-98-TP-2648-S, CV-98-TMP2650-S, 2001 WL 36403362, at *7 (N.D. Ala. Sept. 21, 2001) (finding *Buckman* did not preempt plaintiff's misrepresentation claims because "[t]here is nothing in *Buckman* to suggest that the plaintiffs in that case alleged other grounds for relief, such as fraud on the medical community . . . ."); *cf. Dawson ex rel. Thompson v. Ciba-Gelgy Corp., USA*, 145 F. Supp. 2d 565, 573 (D.N.J. 2001) (where plaintiffs brought class action on behalf of Ritalin users against manufacturer for fraud, misrepresentation and breach of warranties, holding *Buckman* did not create federal question jurisdiction because complaint did not allege a claim of fraud-on-the-FDA, but rather alleged defendants deceived the public, including plaintiffs).

For these reasons, and as further elucidated in the Relators' Opposition, which is incorporated by reference here (*see* note 8, *supra*), the private claims raised in this action in no way preempt the FDCA and, if anything, complement the goals and purpose of the FDA vaccine licensing process.

IV. Plaintiffs Have Standing To Sue Under The Consumer Protection Statutes Of Their Own States And Their Standing To Sue Under The Consumer Protection Statutes Of States Other Than Their Own Should Be Deferred Until Class Certification Proceedings.

In the Second Claim for Relief, Plaintiffs assert claims against Merck for violations of the consumer protection laws of 24 states.[23] In its motion to dismiss, Merck contends that Plaintiffs, who reside in Alabama, New York and New Jersey, lack standing to assert claims "based on consumer protection statutes of states other than their own." (MTD at 22). As set forth below, Merck's Article III challenge to Plaintiffs' standing to sue is without merit. Moreover, Merck's challenge to Plaintiffs' standing to sue under the laws of states other than Alabama, New York and New Jersey is premature, and this Court's determination of those issues should be deferred until Rule 23 class certification proceedings.

There is no doubt that Plaintiffs have alleged facts plausibly demonstrating injury-in-fact sufficient to confer Article III standing to bring consumer protection claims under the laws of New York and New Jersey. The Complaint alleges that Plaintiffs purchased Mumps Vaccine with questionable efficacy, at artificially inflated prices. (CAC ¶¶ 11-14, 37, 124-27, 133 and 155). That is, Plaintiffs personally purchased Mumps Vaccine at artificially inflated prices – a

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[23] On behalf of themselves and the members of the State Consumer Protection Subclass, Plaintiffs assert claims for violations of the consumer protection statutes of the following states: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Idaho, Illinois, Kansas, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Virginia and Washington. (CAC ¶¶ 157, 158(a)-(y) (identifying state statutes)).

monetary injury – which constitutes actual harm. *See, e.g., Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286, 293 (3d Cir. 2005); *In re Processed Egg Prods. Antitrust Litig.*, 851 F. Supp. 2d 867, 887 (E.D. Pa. 2012). This injury can be redressed by the relief sought by Plaintiffs including, *inter alia*, monetary damages to compensate them for their financial harm. Accordingly, Plaintiffs have Article III standing to assert consumer protection claims under the laws of New York and New Jersey. *See id.* at 887-91.

Eschewing this straightforward analysis, Merck asks this Court to find that Plaintiffs lack standing to sue under the consumer protection statutes of the 22 remaining states. (MTD at 22-23). Tellingly, Merck fails to analyze the relevant provisions of each state's consumer protection statute to support its blanket assertion that each such statute requires a plaintiff to have in-state residency or to have made an in-state purchase. In any event, Merck's standing arguments are premature and resolution of this issue should be deferred until class certification issues have been resolved.

In the class action context, named representative plaintiffs initially need only establish that they individually have standing to bring their claims. "The initial inquiry .... is whether the lead plaintiff individually has standing, not whether or not other class members have standing." *Winer Family Trust v. Queen*, 503 F.3d 319, 325-26 (3d Cir. 2007). "Once threshold individual standing by the class representative is met, a proper party to raise a particular issue is before the court, and there remains no further separate class standing requirement in the constitutional sense." *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 306-07 (3d Cir. 1992) (quoting 1 NEWBERG ON CLASS ACTIONS § 2.05 (3d ed. 1992)). As explained in a subsequent edition of that influential treatise:

> In a class action, those represented are, in the words of the Supreme Court, passive members of the class, in contrast to the named plaintiff who is actively prosecuting the litigation in their behalf. These passive members need not make any individual showing of standing, because the standing issue focuses on whether the plaintiff is properly before the court, not whether represented parties or absent class members are properly before the court. *Whether or not the named plaintiff who meets individual standing requirements may assert the rights of absent class members is neither a standing issue nor an Article III case or controversy issue but depends rather on meeting the prerequisites of Rule 23 governing class actions.* The fact that the plaintiff now seeks to represent the rights of absent parties because the case or controversy is common to those parties does not in any way create additional constitutional standing requirements.

William B. Rubinstein et al., 1 NEWBERG ON CLASS ACTIONS § 2:7 (4th ed. 2008) (emphasis added and footnotes omitted).[24]

Courts generally address challenges to standing as a threshold matter; however, in class actions, the Supreme Court has crafted an exception to this general rule: Courts may evaluate class certification issues *before* Article III standing concerns if the former are "logically antecedent" to the latter. *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 831 (1999) (quoting *Amchem Prods. v. Windsor*, 521 U.S. 591, 612 (1997)). Neither the Supreme Court nor the Third Circuit has described the precise circumstances under which class certification logically takes precedence over standing. However, district courts within this Circuit have considered this question on numerous occasions and concluded that:

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[24] "The reason that named plaintiffs in a proposed class action bring claims under consumer protection laws of states where they do not reside is that it allows them to preserve those claims in anticipation of eventually being joined by class members who do reside in the states for which claims have been asserted." *Blessing v. Sirius XM Radio, Inc.*, 756 F. Supp. 2d 445, 452 (S.D.N.Y. 2010). *See also Avenarius v. Eaton Corp.*, No. 11-09-SLR, 2012 WL 4903373, *3 n.5 (D. Del. Oct. 16, 2012).

> The *Ortiz* exception appears "to rest on the long-standing rule that, once a class is properly certified, statutory and Article III standing requirements must be assessed with reference to the class as a whole, not simply with reference to the individual named plaintiff." Accordingly, Rule 23 certification should be addressed first in those cases where it is the possibility of class certification that gives rise to the jurisdictional issue as to standing. Stated differently, the Ortiz exception treating class certification as the antecedent consideration does *not* apply if the standing issue would exist regardless of whether the named plaintiff filed his claim alone or as part of a class.

Clark v. McDonald's Corp., 213 F.R.D. 198, 204 (D.N.J. 2003) (quoting *Payton v. County of Kane*, 308 F.3d 673, 680 (7th Cir. 2002) (other citation omitted)). As interpreted in *Clark*, the Supreme Court's decision in *Ortiz* allows this Court to defer ruling on Article III standing issues where, as here, they are circumscribed by the act of certifying a class.[25]

Similarly reasoned decisions have been issued by district courts within the Second Circuit. In the seminal case, *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002), the defendant drug manufacturer argued that end-payor plaintiffs lacked standing to assert state law antitrust and unfair competition claims against the manufacturer on behalf of prescription drug purchasers nationwide because they only alleged to have purchased the drug in 15 states. Arguing that plaintiffs lacked standing to raise claims under the laws of the other states, the drug manufacturer asserted that this presented an Article III obstacle to the district court's jurisdiction over those state law claims. *See id.* at 377. Rejecting the drug manufacturer's argument, the

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[25] Numerous decisions from the District of New Jersey have reached the same conclusion. *See, e.g., In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 544 (D.N.J. 2004) ("This Court will not address this Article III standing issue prior to determining class certification."); *In re Hypodermic Prods. Antitrust Litig.*, No.05-CV-1602, 2007 WL 1959225, at *15 (D.N.J. June 29, 2007) (rejecting defendant's argument that state law claims should be dismissed because "the named plaintiffs lack standing to bring claims in those states in which the named plaintiffs do not reside or engage in business" because "in accordance with *Ortiz*, the Court will defer its consideration of this argument until after class certification issues have been resolved") (citations omitted).

court stated that "these alleged problems of standing will not arise unless class certification is granted." *Id.* It explained:

> If certification is granted, the proposed class would contain plaintiffs who have personal standing to raise claims under the laws governing purchases in all of the fifty states, and the only relevant question about the named plaintiffs' standing to represent them will be whether the named plaintiffs meet the ordinary criteria for class standing, including whether their claims are typical of those of the class, whether they will adequately represent the interests of the class, and whether there are common legal and/or factual issues that predominate over any differences among the classmembers [sic]. . . .
>
> In any event, this challenge is premature. The parties have not yet briefed the choice of law question, which will determine what state laws govern the claims of the various putative class members whom the End-Payors seek to represent. Hence, the Court cannot yet determine what differences, if any, there are in the legal standards that will apply to the different plaintiffs' claims nationwide.

Id. Numerous district courts within the Second Circuit have followed the reasoning of *Buspirone,* finding that class certification is logically antecedent to standing and, therefore, deferred consideration of standing issues until after class certification issues have been resolved.[26]

The above-referenced precedents from the District of New Jersey and the Southern District of New York were reviewed and, ultimately, followed in *In re Chocolate Antitrust Litig.*,

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[26] *See, e.g.*, *In re Grand Theft Auto Video Game Consumer Litig.,* No. 06 MD 1739(SWK)(MHD), 2006 WL 3039993, at *2-3 (S.D.N.Y. Oct. 25, 2006); *In re DDAVP Indirect Purchaser Antitrust Litig.*, 2012 WL 4932158 at *8-9 (surveying case law before "join[ing] the courts in that growing consensus and find[ing] that class certification is logically antecedent to the issue of standing in this case"); *In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d 390, 406 (S.D.N.Y. 2011); *Blessing v. Sirius XM Radio, Inc.*, 756 at 451 ("While the Second Circuit has not directly addressed the issue, there has been a growing consensus among district courts that class certification is 'logically antecedent,' where its outcome will affect the Article III standing determination, and the weight of authority holds that in general class certification should come first.").

602 F. Supp. 2d 538 (M.D. Pa. 2009), an antitrust case wherein plaintiffs representing indirect end users and indirect purchasers for resale collectively advanced claims arising under the antitrust and consumer protection statutes of 25 states and the District of Columbia. *See id.* at 578. Defendants sought dismissal of plaintiffs' claims under the state laws in which no putative class representative either resided or did business, contending that the named plaintiffs lacked Article III standing to assert such state law claims. The court determined that defendants' challenge to the named plaintiffs' standing was premature:

> In the instant matter, the plaintiffs' capacity to represent individuals from other states depends upon obtaining class certification, and the standing issue would not exist but for their assertion of state law antitrust claims on behalf of class members in these states. Therefore, the standing issues arise from the plaintiffs' attempts to represent the proposed class. These class certification issues are "logically antecedent" to the standing concerns, and the court will defer ruling on the latter until class certification proceedings.

Id. at 579-80 (citations omitted). *Accord Avenarius*, 2012 WL 4903373 at *3 (rejecting defendants' contention that plaintiffs lacked standing because they "do not reside in or claim to have brought trucks in twenty of the states in which they make claims").

Ignoring this nearly unbroken line of precedent, Merck relies on *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143 (E.D. Pa. 2009). (MTD at 22). In that case, the court found that plaintiffs, who were located in Alabama, Illinois, Tennessee and Ohio, "have standing to assert claims only under the laws of those states where the plaintiffs are located." *Id.* at 149; *see also id.* at 157-58. Rejecting the weight of authority – including the above-referenced district court decisions in *Buspirone*, *Clark*, *Hypodermic*, *K-Dur*, *Sheet Metal* and *Chocolate Confectionary* – the court based its conclusion on purported burdens of discovery. *See id.* at 155. Plaintiffs respectfully submit that *Wellbutrin* should not be followed in this case because it is contrary to the great weight of persuasive authority within this Circuit (and within others). Moreover,

Merck cannot demonstrate, and it cannot be found, that the burdens of class certification-related discovery would be any greater if the issue of Plaintiffs' standing to sue under the 23 above-referenced state laws is deferred until Rule 23 class certification proceedings.

V. Plaintiffs Klein And Sutter Have Sufficiently Alleged Consumer Protection Claims Under The Statutes Of Their Respective States

A. Plaintiff Klein Has Alleged A Viable Claim Under New York's Consumer Protection Statute, N.Y. Gen. Bus. Law § 349.

Merck's argument (MTD at 23-26) that Plaintiff Klein has failed to state a claim under New York's consumer protection statute, N.Y. Gen. Bus. Law § 349 ("Section 349")[27] is meritless. Merck argues that Plaintiff Klein has not alleged "consumer-oriented conduct" on the part of Merck, and has not alleged injury to the public interest. (MTD at 24-25). Merck is wrong on both counts.

Whether a defendant's conduct is consumer-oriented is to be "construed liberally." *New York v. Feldman*, 210 F. Supp. 2d 294, 301 (S.D.N.Y. 2002); *see also Marini v. Adamo*, 812 F. Supp. 2d 243, 272 (E.D.N.Y. 2011). New York courts describe "consumer-oriented conduct" as that which is "aimed at the public at large." *Oshy v. Koufa Realty Corp.*, 951 N.Y.S. 2d 87, at *5 (N.Y. Sup. Ct. 2012). This is to be distinguished from private disputes, such as between a landlord and tenant. *See id.*; *see also Lawlor v. Cablevision Sys. Corp.*, 839 N.Y.S. 2d 433, at *3 (N.Y. Sup. Ct. 2007) ("An act or practice is consumer-oriented if it is aimed at the public

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[27] Section 349 "prohibits 'deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service . . . .'" *Blue Cross and Blue Shield of New Jersey, Inc. v. Phillip Morris USA, Inc., et. al.*, 344 F.3d 211, 218 (2d Cir. 2003) (quoting N.Y. Gen. Bus. Law § 349(a)). The statute is "intended to be broadly construed." *State by Lefkowitz v. Colorado State Christian College of Church of Inner Power, Inc.*, 346 N.Y.S.2d 482, 486 (N.Y. Sup. Ct. 1973) (internal quotation and citations omitted). To properly state a claim under Section 349, "a plaintiff must allege that a defendant has engaged in: (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the deceptive act or practice." *City of New York v. Smokes-Spirits.com, Inc.*, 911 N.E.2d 834, 838 (N.Y. 2009).

generally."). Further, "[a] defendant engages in 'consumer-oriented' activity if his actions cause any 'consumer injury or harm to the public interest.'" *Feldman*, 210 F. Supp. 2d at 301 (quoting *Securitron Magnalock Corp v. Schnabolk*, 65 F.3d 256, 264 (2d Cir. 1995)). "[C]ourts have found sufficient allegations of injury to the public interest where plaintiffs plead repeated acts of deception directed at a broad group of individuals." *Id.* (citing *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 175 F. Supp. 2d 593, 631 (S.D.N.Y. 2001)).

Here, Plaintiff Klein repeatedly alleges that Merck misled the public and the U.S. government by representing a falsely inflated efficacy rate for its Mumps Vaccine when it knew that the vaccine had diminished in efficacy. (CAC ¶¶ 27, 83, 84, 102, 103). The Complaint also alleges that Merck submitted fraudulent test results to the FDA. (CAC ¶¶ 9, 10, 53, 64, 69, 71-80, 87-88, 93, 146, 152), the direct effect of which was to maintain FDA approval so that Merck could sell its Mumps Vaccine to the public. Such allegations constitute the requisite consumer-oriented conduct because the misrepresentations were directed to the public at large and resulted in the public paying for and being administered a vaccine that was nowhere nearly as effective as represented by Merck. (CAC ¶ 33). Likewise, this consumer-oriented conduct presented harm to the public interest in New York and throughout the United States because it left the public susceptible to mumps outbreaks, which have already occurred twice and continue to present a significant risk of resurgence. (CAC ¶¶ 95-110).[28]

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[28] The cases cited by Merck (MTD pp. 23-26) are misplaced. First, *In re: Rezulin Prods. Liab. Litig.*, 390 F. Supp. 2d 319 (S.D.N.Y. 2005) is inapplicable at this stage of the litigation because the court in that