IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC., et al.,	
Plaintiffs,	
v.	**Civ. No. 12-3824**
	Applies to All Actions
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,	
Defendants.	

DEFENDANTS' MEMORANDUM IN OPPOSITION TO FEDERAL TRADE COMMISSION'S MOTION FOR LEAVE TO FILE AMICUS BRIEF

TABLE OF CONTENTS

Defendants Warner Chilcott and Mayne[1] submit this memorandum in opposition to the Federal Trade Commission's motion for leave at the district court level to file an *amicus* brief in support of Mylan's position on the pending motions to dismiss. The FTC's proposed *amicus* submission ("FTC Brief"), filed by the Health Care Division staff in the middle of the briefing on the motions to dismiss here, adds nothing to this private litigation but the Commission's partisan enforcement views and badly mischaracterizes Defendants' position. Also, the FTC's submission duplicates the advocacy already presented by Mylan. Permitting the FTC to file its brief only would complicate this matter, without benefit to the Court or the parties.

The Federal Rules of Civil Procedure do not address *amicus* briefs (only the appellate rules do), and at least 12 district courts — 3 in this District — have denied motions for leave to file *amicus* briefs like this one. This Court should reject the FTC's motion, just as the U.S. District Court for the District of New Jersey did last month in a case (filed by many of the same plaintiffs' counsel here) that also asserts antitrust claims regarding allegedly delayed entry of generic pharmaceuticals. *See Prof'l Drug Co. v. Wyeth Inc.*, Civ. A. No. 11-5479 (JAP), 2012 WL 4794587 (D.N.J. Oct. 3, 2012) (denying FTC's motion for leave to file *amicus* brief in case alleging conduct that delayed entry of generic versions of anti-depressant Effexor).

The FTC Health Care Division argues that it offers its "unique" perspective to the Court by providing "history and context" on the pharmaceutical industry, but in fact it presumptuously seeks to do the Court's job, boldly concluding (in its only paragraph of "analysis") that Plaintiffs "have stated a plausible claim" and that Plaintiffs' allegations "are sufficient to state a claim" for relief. FTC Brief at 14.

[1] "Defendants" are Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Company, LLC, Warner Chilcott (US), LLC, Warner Chilcott Holdings Company III, Ltd., and Warner Chilcott Public Limited Company (collectively, "Warner Chilcott"), Mayne Pharma Group Limited, and Mayne Pharma International Pty. Ltd. (collectively, "Mayne").

The FTC sheds no light on any legal issue; the FTC brief in fact confirms that the only court in the U.S. ever to hold that "product hopping" conduct was an antitrust violation was *TriCor*. But the FTC fails to inform the Court that the Commission investigated Abbott regarding the alleged TriCor "product hopping" and the FTC concluded that Abbott's actions there were not worthy of bringing an antitrust action and closed its TriCor investigation. The FTC also does not address any of the arguments made by Defendants as to why *TriCor* cannot govern this case and fails to address the more recent and more analogous cases that have dismissed such "product hopping" theories (*e.g.*, *Walgreens* and *AstraZeneca*) on the pleadings. The FTC does not even cite a single new case on "product hopping" or the application of the antitrust laws to new products that is not already cited and discussed by the parties.

Nor does the FTC Health Care Division staff attempt to address any of the other difficult questions Defendants have raised in their motions to dismiss. The proposed *amicus* brief appears to assume that "product switching" is anti-competitive, yet it never answers how any pharmaceutical firm could market a new drug without seeking doctors to "switch" to the new drug. Every manufacturer that introduces a new drug seeks to "switch" customers to the new product. This switching is called competition. Nor does the Health Care staff address related issues such as how "innovative" is innovative enough for a new drug, or how a lawyer possibly can counsel a client on whether a new product is sufficiently "innovative" or "novel" to avoid expensive litigation and a jury trial — questions Defendants posed in their motions.

The FTC does not claim to have performed any study of Doryx or of the broad market for acne products. Nor does the FTC claim to have studied the anti-competitive impact of granting the relief sought by Plaintiffs here, namely, that a ban on new versions of Doryx would leave Mylan as the sole generic free from competition in its self-serving Doryx-only product market.

Further Doryx innovation would be banned if the requested relief was granted, and patients and prescribers in the United States would be limited to the dosage strengths and versions of Doryx that currently exist. Ultimately, since the FTC adds nothing of substance either factually or legally, and has demonstrated no specialized knowledge regarding "product switching" or the acne market, it appears the FTC is simply attempting to promote a policy agenda or flex its muscle as an enforcement agency. An *amicus* brief at the district court level is an inappropriate tool to serve either goal.

Permitting the FTC to submit its brief only would add expense and further complicate this matter with no benefit to the Court or the parties. The Court already has nearly 350 pages of briefing before it on the motions to dismiss — including over 200 pages from Plaintiffs supporting the position advocated by the FTC — without the FTC's submission and responses thereto, and briefing is not yet completed. The Court should deny the FTC's motion.

BACKGROUND

As the Court is aware, this case involves claims by Mylan and various proposed class plaintiffs that Warner Chilcott and its licensor, Mayne, violated the antitrust laws by obtaining FDA approval for and launching new versions of Doryx. Plaintiffs allege that, even though Defendants complied with all applicable rules and regulations in launching their new products and in ceasing to promote their old versions, Mylan — a leading seller of branded and generic drugs, which itself markets multiple versions of its products — could not "keep pace with" Warner Chilcott, and therefore generic competition was unlawfully "delayed." Plaintiffs have not indicated whether they will ask the Court to order Defendants to remove their products from the market, to detail and promote all their old versions in perpetuity, or both.

Plaintiffs also seek to *prevent future competition* for Mylan's doxycycline hyclate DR products by this lawsuit. Mylan argues that future versions of Doryx (such as new dosage strengths) also would represent "product-hopping" and should trigger crippling treble damages for any new version of Doryx. Mylan Compl. ¶¶ 6, 73-77, Prayer for Relief ("further relief"). Mylan is the sole generic manufacturer of Doryx to have received FDA approval and launched its generic Doryx products, so it has an exclusive position in the sale of generic doxycycline hyclate DR products that would be further entrenched by the relief Plaintiffs seek in this case. The Indirect Plaintiff specifically prays for an injunction barring the challenged conduct, including the launch of new Doryx versions (Indirect Compl. ¶¶ 95-97), to block similar conduct from occurring "in the future." Prayer for Relief ¶ 5.

The FTC Brief never comes to grips with this avowedly anticompetitive aspect of Plaintiffs' Complaints. A ban on new versions of Doryx, and treble damages for every dollar in sales or profits of a new drug later found not to be sufficiently "innovative," would chill new product development and other innovation.

ARGUMENT

Whether to accept the FTC's proposed brief is solely within the Court's discretion. *See Price v. Corzine*, Civ. A. No. 06-1520, 2006 WL 2252208, at *2 (D.N.J. Aug. 7, 2006) ("District courts have the inherent authority to appoint amicus curiae to assist in their proceedings.") (citations omitted); *Waste Mgmt. of Pa., Inc. v. City of York*, 162 F.R.D. 34, 36 (M.D. Pa. 1995) ("The extent, if any, to which an amicus curiae should be permitted to participate in a pending action is solely within the broad discretion of the district court.") (citations omitted). "At the trial level, where issues of fact as well as law predominate, the aid of amicus curiae may be *less*

appropriate than at the appellate level." *U.S. v. Alkaabi*, 223 F. Supp. 2d 583, 592 n.16 (D.N.J. 2002) (emphasis added).

District courts in the Third Circuit have looked to the application of Federal Rule of Appellate Procedure 29, which governs the appearance of *amici* in the Courts of Appeals, when considering whether to accept a submission from a proposed *amicus curiae*. *See, e.g., Prof'l Drug*, 2012 WL 4794587, at *1-2 (reviewing factors and rejecting FTC *amicus* brief in pharmaceutical antitrust litigation). A motion for leave to file an *amicus curiae* brief may be granted when: (1) the proposed *amicus curiae* has a "special interest" in the particular case; (2) that interest is not already being represented in the case; (3) the proposed submission is useful and timely; and (4) the proposed *amicus curiae* is not partial to a particular outcome in the case. *See Prof'l Drug*, 2012 WL 4794587, at *1; *Liberty Res., Inc. v. Phila. Hous. Auth.*, 395 F. Supp. 2d 206, 209 (E.D. Pa. 2005).

I. At Least Twelve District Courts Have Rejected Similar Efforts by the FTC and Others to File *Amicus* Briefs

Applying these factors, the District Court for the District of New Jersey recently rejected a similar motion by the FTC in a private antitrust lawsuit involving the anti-depressant Effexor. *See Prof'l Drug*, 2012 WL 4794587, at *2. There, as here, the FTC argued that it sought to intervene to offer its unique perspective and expertise to the court — on the issue of brand-generic patent settlement agreements alleged to have delayed generic entry — but the court denied the FTC's motion. The *Professional Drug* court held that, among other things, "the FTC has not expressed an interest that is not represented competently in this case" and that "the extent to which the FTC is partial to a particular outcome weighs against granting the agency's motion." *Id.* at *2. Importantly, the FTC's proposed *amicus* brief here is even more partisan than the brief rejected in *Professional Drug*, where the FTC at least refrained from taking a

position on how the court should rule on the pending motions to dismiss. Here (as discussed below, in a case pursued by the Health Care staff's alumnus, Mr. Silber), the FTC explicitly requests that the Court rule in favor of Mylan on the pending motions.

Indeed, at least 12 district courts have denied motions for leave to file *amicus* briefs such as the FTC's here, including 3 cases in this District. *See Prof'l Drug*, 2012 WL 4794587, at *2; *Price*, 2006 WL 2252208, at *2 (denying FTC's *amicus* brief in private pharmaceutical antitrust suit); *Abu-Jamal v. Horn*, Civ. A. No. 99-5089, 2000 WL 1100784, at *1, 5 (E.D. Pa. Aug. 7, 2000) (denying leave to file *amicus* brief, where "Petitioner has highly experienced and qualified counsel who have identified the principle legal issues which amici curiae ask to brief"); *T.B. Proprietary Corp. v. Sposato Builders, Inc.*, Civ. A. No. 94-6745, 1996 WL 674010, at *4 (E.D. Pa. Nov. 20, 1996) (denying leave to file *amicus* brief, where counsel "has argued its motion ably and vigorously"); *Goldberg v. City of Philadelphia*, Civ. A. No. 91-7575, 1994 WL 369875, at *1 (E.D. Pa. July 14, 1994) (denying leave to file *amicus* brief, where plaintiff "appears to be adequately represented by his counsel," the *amicus curiae* "appears to be a friend of the Plaintiffs, not a friend of the Court"); *Liberty Lincoln Mercury, Inc. v. Ford Mktg. Corp.*, 149 F.R.D. 65, 83 (D.N.J. 1993) (denying NJADA and FDA's motions for leave to file *amicus* brief, where parties had "capably briefed the relevant issues"); *Wis. Educ. Assoc. Council v. Walker*, 824 F. Supp. 2d 856, 861 (W.D. Wis. 2012) (denying groups' motions for leave to file *amicus* briefs where court "specifically warns against attempts by amicus curiae to inject interest-group politics into the federal courts"); *De Abadia-Peixoto v. U.S. Dep't of Homeland Sec.*, 277 F.R.D. 572, 576 (N.D. Cal. 2011) ("Because the motion to dismiss presents purely legal issues as to the sufficiency of the pleadings, any unique perspectives or information the proposed *amici* might have to offer are not especially pertinent at this juncture. Plaintiffs are represented by competent

counsel who have ably addressed the relevant legal issues."); *N.C. State Bd. of Dental Exam'rs v. FTC*, 768 F. Supp. 2d 818, 825 (E.D.N.C. 2011) (denying four State Boards of Dental Examiners' motions for leave to file *amicus* briefs); *Conservancy of S.W. Fla. v. U.S. Fish & Wildlife Serv.*, No. 2:10-cv-106, 2010 WL 3603276, at *1 (M.D. Fla. Sept. 9, 2010) (denying leave for *amicus* status to Florida Wildlife Federation where *amicus* brief was not relevant to motion to dismiss and would not be useful to court); *United States v. Gotti*, 755 F. Supp. 1157, 1159 (E.D. N.Y. 1991) ("Rather than seeking to come as a 'friend of the court' and provide the court with an objective, dispassionate, neutral discussion of the issues, it is apparent that the NYCLU has come as an advocate for one side . . . [and] does the court, itself and fundamental notions of fairness a disservice."); *Leigh v. Engle*, 535 F. Supp. 418, 422 (N.D. Ill. 1982) (denying leave to file *amicus* brief, where court determined brief to be "a memorandum amicus petitor, one proffered as a friend of the plaintiff(s)").

II. The Court Should Deny the FTC's Request for Leave to File Its Proposed *Amicus* Brief Here

The factors above weigh heavily against accepting the proposed brief.

A. The FTC Has No Special or Unique Interest in This Particular Dispute

1. This Case Does Not Involve FTC Regulations

This case does not involve the interpretation of any FTC regulation, the quintessential reason a regulatory agency might be permitted to submit an *amicus* brief. The FTC does not claim to have performed any investigation of Doryx or of the market for the treatment of acne, nor does it claim to have studied the competitive dynamics at play here or the implications of the relief sought by Plaintiffs (prohibition of new dosage strengths or forms of Doryx).

2. The FTC Investigated and Closed the *TriCor* Case Taking No Enforcement Action Whatsoever – A Fact Not Disclosed to this Court

The FTC brief does confirm one fact: the only "product hopping" case that proceeded past a motion to dismiss is *TriCor*. FTC Brief at 13-14. But significantly, the FTC elects not to inform this Court that the Commission's Health Care Division — during the tenure of Mr. Meier (the brief's author) — did investigate "product hopping" with Abbott's TriCor. *See, e.g.*, "TriCor Case May Illuminate Patent Limits," *Wall Street Journal*, June 2, 2008 ("Product switching isn't against the law, but the states' lawsuit alleges that Abbott acted improperly by employing it and other strategies solely to preserve its monopoly on TriCor. The Federal Trade Commission is investigating the same issue.").[2] The FTC also elects not to inform the Court in its brief that the FTC's conclusion in the TriCor matter was that the Commission should close that investigation without taking any enforcement action; the FTC did not see the alleged "product hopping" conduct in that case as deserving enforcement action by the Commission.

3. The FTC Fails to Address Anticompetitive Effect of Plaintiffs' Complaints

Plaintiffs allege that each new dosage strength or new version of Doryx "excluded" competition, even though Plaintiffs do not allege any behavior such as the manipulation of NDDF or other listing codes to *actually prevent* prescriptions of Mylan's generic Doryx. In fact, Mylan's Complaint admits that it successfully launched its competing versions of the 75mg, 100mg, and 150mg generic Doryx tablets once the company received FDA approval to do so, without any blocking of that approval by Defendants. Mylan Compl. ¶¶ 4, 60, 63, 71, 85. Mylan also challenges as illegal any future launches of new versions of Doryx by Warner Chilcott (*id.* at ¶¶ 6, 73-76), such that, if those new versions were deemed illegal by the Court, Mylan would further entrench its position as the sole generic seller of doxycycline hyclate DR.

[2] Available at http://online.wsj.com/article/SB121236509655436509.html.

The FTC claims no special insight or perspective on how such relief, if granted, would impact the parties or competition in the acne business. The FTC brief also does not come to grips with the fact that these complaints pray for or would have the effect of banning new dosage strengths or forms of Doryx. The Mylan Complaint would impose $3 of damages for each $1 of profits that a new Doryx form would earn and prays for additional relief against future Doryx; the Indirect Plaintiff comes out and asks for a ban on future Doryx doses. The FTC has never sought such relief and no court has ever granted such relief — banning a future dosage strength of an FDA approved drug.

4. The FTC Has No Special Right or Entitlement to File an *Amicus* Brief in This Action

Moreover, the FTC has no inherent right to file a brief in this matter. Nor is the FTC entitled to drop in *amicus* briefs in district courts simply by virtue of the fact that it is a government agency. Because it acts here as an advocate for a litigation position rather than a neutral agency, the FTC is due no deference in this proceeding. *See Chavez-Rivas v. Olsen*, 207 F. Supp. 2d 326, 332 (D.N.J. 2002). The FTC's *amicus* brief seeks only to promote an interpretation of the Sherman Act, a role clearly committed to and within the core competency of this Court. Unlike where a government agency offers an interpretation of its own regulations, such that courts must grant *Chevron* deference, *Chase Bank USA, N.A. v. McCoy*, 131 S. Ct. 871, 880 (2011), *Auer v. Robbins*, 519 U.S. 452, 461 (1997), here the agency merely advocates for a particular litigation outcome. *See, e.g., M. Fortunoff of Westbury Corp. v. Peerless Ins. Co.*, 432 F.3d 127, 139 (2d Cir. 2004) (deference due only to extent that *amicus* brief interpreted FMCSA's own regulations); *Keys v. Barnhart*, 347 F.3d 990, 993-94 (7th Cir. 2003) ("In any event, we doubt that *Chevron* has any role to play in this case because the government's brief did not offer an interpretation of the agency's regulations.").

B. Plaintiffs Are Well Represented, and the FTC's Position That the Mylan Complaint Should Not Be Dismissed Is Already Being Advocated

The FTC's interest already is being represented by competent counsel experienced in these cases; the Plaintiffs have filed more than 200 pages in opposition to the pending motions to dismiss. Mylan is represented by, among others, Jonathan Jacobson and Seth Silber of the Wilson Sonsini firm. Both are experienced antitrust litigators, and Mr. Silber is an alumnus of the FTC's Health Care Division, the same group that drafted the proposed *amicus* brief, and, notably, Mr. Silber served in that FTC Division with the two lead draftsmen of the FTC brief, Mr. Meier and Mr. Albert.[3] Strikingly, the only Complaint analysis offered by the FTC comes in a single, cursory paragraph (at 14) and is limited to the complaint of Mr. Silber's client, Mylan; the FTC makes no comment on the Direct Purchaser or Indirect Purchaser (IBEW) Complaints.

Class Plaintiffs are represented by a large group of lawyers from various firms with extensive experience in pharmaceutical antitrust litigation. Apparently seeking tens or even hundreds of millions of dollars, these Plaintiffs have every financial interest and incentive to prosecute this case aggressively and advance the FTC's apparent view — which Defendants vigorously oppose — that promoting new FDA-approved pharmaceuticals and ceasing to promote old versions is illegal under the antitrust laws. *See, e.g.*, *Prof'l Drug*, 2012 WL 4794587, at *2 (denying leave to file *amicus* brief, where "the FTC has not expressed an interest that is not represented competently in this case"); *Price*, 2006 WL 2252208, at *3 (denying ACLU-NJ's *amicus* brief; its participation would not be useful to court and plaintiffs adequately were represented by competent counsel); *Abu-Jamal*, 2000 WL 1100784, at *1, 5 ("Petitioner

[3] Together, the three FTC staff lawyers (Mr. Meier, Mr. Silber, and Mr. Albert) conducted a 40-day trial in the *K-Dur* case for 40 days before the FTC's own Administrative Law Judge. The ALJ rejected the FTC staff challenge (*see In the Matter of Schering Plough*, FTC Initial Decision, Docket No. 9297 (June 27, 2002) (ALJ Chappell), *available at* http://www.ftc.gov/os/adjpro/d9297/020627id.pdf), a decision upheld by the Eleventh Circuit. *See Schering Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

has highly experienced and qualified counsel who have identified the principal legal issues which amici curiae ask to brief."); *Leigh*, 535 F. Supp. at 422 (denying Secretary of Labor leave where Secretary filing not as "friend of the court" but rather "friend of the plaintiff").

C. The FTC Brief Adds Nothing of Substance to the Motion to Dismiss Arguments and Is Not Useful

The FTC brief contributes nothing of substance to the analysis of the pending motions to dismiss. Other than its self-congratulatory reference (at 3 & n.10) to three cases citing FTC studies involving conduct unrelated to that alleged in this case, and involving legal holdings that are irrelevant here, the FTC mentions only two cases not already cited in the parties' briefing, and even there only in passing. The FTC's entire analysis of the Mylan Complaint is confined to a single cursory and conclusory paragraph (at 14), advocating that Mylan has stated a claim for relief. The FTC wholly ignores the Direct and Indirect Purchaser complaints.

The FTC relies primarily on publicly-available (and often outdated) studies and reports, along with case law that only confirms that the only case ever to have held that pharmaceutical "product switching" may be an antitrust violation is the single Delaware district court case (*TriCor*, involving registry code manipulation and other facts not alleged here) already cited extensively by Plaintiffs. The FTC fails to cite any cases not already cited by the parties on the issues of "product switching" or the antitrust treatment of new products. And like Mylan, the FTC conspicuously ignores the Supreme Court's decision in *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2012), which not only found the sort of marketing of branded products ("detailing") about which Plaintiffs complain to be constitutionally-protected speech, but also recognized the

educational benefits to physicians of such speech (and of "counter-detailing" speech by generic manufacturers like Mylan).[4]

The FTC reveals itself as a partisan in its failure to cite cases that are on point. The FTC's reliance on the single *TriCor* case, while omitting any discussion of the two more recent and analogous "product hopping" cases (*Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 148, 151 (D.D.C. 2008), and *AstraZeneca AB v. Mylan Labs. Inc.*, Nos. 00 Civ. 6749, 03 Civ. 6057, 2010 WL 2079722, at *6 (S.D.N.Y. May 19, 2010)), that dismissed the plaintiffs' complaints, either demonstrates a lack of knowledge of the relevant case law, or a partisanship inappropriate for an *amicus curiae*, as discussed below.

D. The FTC Is Explicitly Partial to Mylan in This Case

As the court in *Professional Drug* held, the FTC is partial to a particular outcome in this litigation. And the FTC Brief itself makes this very clear. As noted above, in two different places the FTC comes out and admits that it is asking this Court to conclude that Plaintiffs have a stated a claim:

> The FTC respectfully submits that, like the plaintiffs in *Tricor*, plaintiffs in this case *have stated a plausible claim* . . . .
>
> [Plaintiffs' allegations] are *sufficient to state a claim* of exclusionary conduct.

FTC Brief at 14 (emphasis added). This attempted usurpation of the Court's authority is extraordinary and should be rejected. But at the very least it removes any guise of impartiality by the FTC here, and raises the question why the FTC should take a position in this case having itself rejected any federal enforcement role in *Abbott/TriCor*.

Similarly, the manner in which the FTC mischaracterizes Defendants' positions in this case to support its arguments exposes the Commission's partiality for one side. For example, in

[4] Instead, the FTC simply relies on articles from 2000 and 2007 (FTC Brief at 6 & n.20), before *Sorrell*, in support of its assertion that physicians are simply ignorant about the costs of pharmaceuticals.

multiple places the FTC claims that Defendants advocate a position that product changes are "per se lawful." FTC Brief at 1, 13-14. That is simply untrue. As discussed in Warner Chilcott's brief in support of its motion to dismiss, while Plaintiffs advocate that all new pharmaceutical products be tested by courts and juries for whether they are sufficiently innovative, Warner Chilcott acknowledges that past courts interpreting Section 2 of the Sherman Act provide a limiting principle for these cases. Specifically, as *Berkey Photo* (2d Circuit), *Allied Orthopedic* (9th Circuit), *Walgreen* (District of D.C. in "product-hopping" case), *ILC Peripherals* (N.D. Cal.), and other cases make clear, the antitrust laws should not get involved in new product launches or other innovation unless an element of coercion (bundling, tying, exclusive dealing) is present. Warner Chilcott Mem. at 21-23, Docket Entry No. 84. And Plaintiffs here make no allegation of coercion whatsoever. The word "coercion" or a variation thereof does not even appear in any of their three lengthy complaints.

The FTC also mischaracterizes the alleged conduct in this case to support the *amicus* brief's "holding" that Plaintiffs have stated a claim: "The allegations that defendants used product reformulations to *manipulate the pharmaceutical regulatory system* and thereby suppress generic competition are sufficient to state a claim of exclusionary conduct." FTC Brief at 14 (emphasis added). Nowhere in any of the complaints do any of the Plaintiffs allege that Defendants violated any rule of the "pharmaceutical regulatory system," made a false statement to the FDA or anyone else, or otherwise broke the laws governing pharmaceutical approvals or sales in any way. The only plaintiff that came close — the Indirect Plaintiff (IBEW) — disclaimed any falsehood or misrepresentation was made to doctors or to the FDA in their Opposition, a fact missed by the FTC in its cursory review of the pleadings in this case. The

FTC's straining to suggest otherwise only exposes the shortcomings of Plaintiffs' claims. In any event, it confirms the FTC is partial to one side of this litigation.

Although courts retain discretion in the treatment of *amicus* filings, they generally deny leave when the *amicus* submission seeks simply to advocate a litigation position rather than provide guidance on the issues before the court. *See Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063-64 (7th Cir. 1997); *Strasser v. Doorley*, 432 F.2d 567, 569 (1st Cir. 1970); *Liberty Lincoln Mercury*, 149 F.R.D. at 82-83. As one court warned, "[t]he vast majority of amicus curiae briefs are filed by allies of litigants and duplicate the arguments made in the litigants' briefs, in effect merely extending the length of the litigant's brief. Such amicus briefs should not be allowed. They are an abuse. The term 'amicus curiae' means friend of the court, *not friend of a party*." *Ryan*, 125 F.3d at 1063 (emphasis added). Therefore, all four factors weigh against the FTC's position in this case, and the motion for leave should be denied.

III. Even if Accepted, the FTC's *Amicus* Brief Adds Nothing and Does Not Support Denying the Motions to Dismiss

If the Court nonetheless is inclined to accept the FTC's proposed brief, Defendants submit that the brief adds nothing and does not support denying the motions to dismiss. The FTC offers no special perspective on the acne market or other critical aspects of this case that render Plaintiffs' claims implausible. Nor does the FTC say anything about antitrust injury, causation, market definition, *Noerr-Pennington* immunity for the regulatory filings at issue here, or the other dispositive issues here. The FTC is also entirely silent on the patent court's ruling that the Doryx Tablet Patent ('161) was a valid invention and that the new tablet form offered stability benefits over the prior art.

The FTC Brief does nothing to change the fact that all of Plaintiffs' claims should be dismissed now.

The FTC has tremendous resources and is fully capable of investigating and prosecuting conduct, including launches of new pharmaceutical products, if it believes the facts and market dynamics support such action. The FTC should not be permitted to officiously comment in this private dispute.

CONCLUSION

For the foregoing reasons, Defendants respectfully ask that the Court deny the FTC's motion for leave to file an *amicus* brief.

Respectfully submitted this 23rd day of November, 2012.

By: /s/ J. Mark Gidley

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CERTIFICATE OF SERVICE

I, Lindsay E. Leonard, hereby certify that on November 23, 2012, I caused true and correct copies of the foregoing Defendants' Memorandum in Opposition to Federal Trade Commission's Motion for Leave to File Amicus Brief to be served through the CM/ECF system upon all counsel of record and by electronic mail to the Federal Trade Commission.

Dated: November 23, 2012

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