IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs and Counterclaim-Defendants, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants and Counterclaimants	Civil Action No. 18-1994 (FLW) (TJB) **NOTICE OF MOTION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE*** Motion Date: July 2, 2018

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TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on July 2, 2018 at 10:00 a.m., or as soon as the Court may allow, the undersigned counsel for non-party the Federal Trade Commission (FTC) shall move the Court at the Clarkson S. Fisher Building & U.S. Courthouse, 402 East State Street, Trenton, New Jersey, before the Honorable Freda L. Wolfson, United States District Judge, for an Order granting the FTC leave to file a brief as *amicus curiae* with respect to Plaintiffs and Counterclaim-Defendants' motion to dismiss.

PLEASE TAKE FURTHER NOTICE that the FTC will rely upon the attached Memorandum of Law in Support of Motion for Leave to File a Brief as *Amicus Curiae*, the proposed *amicus* brief, and the proposed Order, which are electronically filed and submitted herewith.

Dated: June 6, 2018

Respectfully submitted,

s/ *Kara L. Monahan*

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TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs and Counterclaim-Defendants, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants and Counterclaimants	Civil Action No. 18-1994 (FLW) (TJB) Motion Date: July 2, 2018

MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE*

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The Federal Trade Commission (FTC) respectfully moves for leave to file an *amicus curiae* brief in the above-captioned matter in connection with Takeda's pending motion to dismiss Zydus's antitrust counterclaims (Dkt. No. 33).[1] Defendant-counterclaimant Zydus consents to the FTC's filing of an *amicus* brief. Takeda does not oppose the submission of an *amicus* brief by the FTC and reserves the right to address in its reply brief any positions taken, or arguments made, by the FTC in its *amicus* brief.

This case raises an important issue about the application of the *Noerr-Pennington* doctrine in the pharmaceutical industry.[2] Defendant Zydus has asserted antitrust counterclaims against Takeda alleging that Takeda's patent-infringement lawsuit is a sham. Takeda has argued in response that Zydus's antitrust counterclaims must fail because, among other reasons, Takeda's suit was filed under provisions of the Hatch-Waxman Act that permit brand drug manufacturers to sue generic companies for a technical act of patent infringement prior to the generic's market entry.

The FTC seeks leave to submit a brief as *amicus curiae* to assist the Court with its analysis of this issue. The FTC, an independent federal agency charged

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[1] "Zydus" refers to Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited. "Takeda" refers to Takeda Pharmaceutical Company Limited; Takeda Pharmaceuticals USA, Inc.; and Takeda Pharmaceuticals America, Inc.

[2] *See United Mine Workers v. Pennington*, 381 U.S. 657 (1965); *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961).

with promoting a competitive marketplace and protecting consumer interests, exercises primary responsibility for federal antitrust enforcement in the pharmaceutical industry. The FTC has a substantial interest in the application of the *Noerr-Pennington* doctrine, including with respect to the pharmaceutical industry.[3] The FTC has substantial experience regarding the framework for generic drug approval and competition under the Hatch-Waxman Act.[4] The FTC has investigated allegations that manufacturers of brand-name pharmaceutical products have engaged in sham petitioning, including the filing of sham Hatch-Waxman patent litigation, and has used its law enforcement authority to challenge anticompetitive Hatch-Waxman suits.[5]

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[3] *See generally* FED. TRADE COMM'N STAFF, ENFORCEMENT PERSPECTIVES ON THE *NOERR-PENNINGTON* DOCTRINE (2006), *available at* https://www.ftc.gov/sites/default/files/documents/reports/ftc-staff-report-concerning-enforcement-perspectives-noerr-pennington-doctrine/p013518enfperspectnoerr-penningtondoctrine.pdf.

[4] *See generally* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002), *available at* https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf; FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT (August 2011), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[5] *See, e.g.*, *FTC v. AbbVie Inc.*, No. 14-cv-5151, 2017 WL 4098688 (E.D. Pa. Sept. 15, 2017).

I. District Courts Have Broad Discretion to Appoint an *Amicus Curiae*

"District courts have broad discretion to appoint *amicus curiae*."[6] "Although there is no rule governing the appearance of *amicus curiae* in the United States District Courts," some district courts in the Third Circuit have looked to the Federal Rules of Appellate Procedure for guidance in exercising their broad discretion.[7] Rule 29 distinguishes between *amicus* briefs filed by federal government agencies and those filed by private parties. *Amicus* briefs from federal agencies are accepted by Courts of Appeals as a matter of right,[8] and have been accepted by some district courts solely on this basis.[9] *Amici* from federal agencies offer a distinctive perspective because "governmental bodies, acting as *amicus curiae*, possess unparalleled institutional expertise and constitute a valuable means of determining how the court's decision may affect the world outside its chambers."[10] In contrast, for private *amici*, Rule 29 requires that, unless all parties consent to its filing, the *amicus curiae* obtain leave of the court after showing that

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[6] *Sciotto v. Marple Newtown Sch. Dist.*, 70 F. Supp. 2d 553, 555 (E.D. Pa. 1999) (quoting *Liberty Lincoln Mercury, Inc. v. Ford Mktg. Corp.*, 149 F.R.D. 65, 82 (D.N.J. 1993)); *see also Avellino v. Herron*, 991 F. Supp. 730, 732 (E.D. Pa. 1998).

[7] *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002).

[8] *See* FED. R. APP. P. 29(a).

[9] *See, e.g., Clark v. Actavis Group HF*, 567 F. Supp. 2d 711, 718 n.11 (D.N.J. 2008) (*amicus* brief filed by U.S. Department of Justice).

[10] Michael K. Lowman, *The Litigating Amicus Curiae: When Does the Party Begin After the Friends Leave?*, 41 AM. U. L. REV. 1243, 1261-62 (1992).

its brief is timely and expresses an interest relevant to the disposition of the case.[11]

District courts in this Circuit have also applied a four-part standard that incorporates principles similar to Rule 29 as well as other factors, including one considering the "partiality" of the would-be *amicus*.[12] These courts grant leave to participate as *amicus curiae* when: (1) the *amicus* has a "special interest" in the particular case; (2) the *amicus*'s interest is not represented competently or at all in the case; (3) the proffered information is timely and useful; and (4) the *amicus* is not partial to a particular outcome in the case.[13]

II. This Court Should Exercise Its Discretion to Accept the FTC's *Amicus* Brief

The FTC respectfully requests that the court exercise its discretion to accept its *amicus* brief because (1) the brief expresses both public and governmental interests of a federal agency charged with protecting consumers from unfair competition; (2) these interests are not currently represented before the Court; (3) the information proffered is useful and timely; and (4) the FTC is not partial to any specific outcome in the case.

First, the FTC is a federal agency representing the public interest with the

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[11] FED. R. APP. P. 29(a), (b), (e)*; see also Neonatology Assocs., P.A. v. Comm'r of Internal Revenue*, 293 F.3d 128, 130-31 (3d Cir. 2002).

[12] *See, e.g., Liberty Res., Inc. v. Phila. Hous. Auth.*, 395 F. Supp. 2d 206, 209 (E.D. Pa. 2005) (citing *Sciotto*, 70 F. Supp. 2d at 555).

[13] *United States v. Bayer Corp.*, No. CV 07-0001 (JLL), 2014 WL 12625934, at *1 (D.N.J. Oct. 23, 2014) (citing *Sciotto, supra*).

goal of preserving competition and protecting consumers from violations of the antitrust laws. As outlined in the FTC's *amicus* brief, Takeda's argument that Hatch-Waxman suits are categorically exempt from scrutiny as alleged shams would—if adopted—have serious long-term implications for *all* consumers, not just the private parties in this matter. Moreover, as an agency charged by Congress with enforcing competition laws, and as the primary antitrust enforcer in the pharmaceutical industry, the FTC has a special interest in the interpretation of laws impacting generic drug competition. District courts consider these interests when granting motions for leave to federal agencies to participate as *amicus curiae*.[14]

Second, the FTC's interest, and the interest of consumers in general, may not be adequately represented by the private parties to this litigation because each of the parties is charged with representing its own interests. Unlike the parties, whose interests are focused on the outcome of this particular case, the FTC has broader interests in the application of antitrust law in the pharmaceutical industry and the potential ramifications for consumers of prescription drugs. The FTC's unique perspective as a government agency may aid the court in its analysis of the issues

[14] *See, e.g., Waste Mgmt. of Pa., Inc. v. City of York*, 162 F.R.D. 34, 37 (M.D. Pa. 1995) (stating as a basis for accepting an *amicus* brief that "the EPA has a special interest in this litigation as it is the primary body responsible for administering and enforcing" the relevant law).

in this case.[15]

Third, the brief provides useful information based on the FTC's extensive knowledge of generic drug competition in a manner that is timely and allows defendants sufficient opportunity to respond. As described in the *amicus* brief, the FTC has a unique institutional perspective to offer the Court in its analysis of the competitive implications of the allegations raised in this case. The *amicus* brief outlines the relevant regulatory structure and explains how the regulatory setting may influence the antitrust analysis. The FTC's brief is timely and provides ample time for Takeda to respond.

Fourth, while the FTC is interested in the development of the law in this area, it takes no position on the ultimate outcome in this case. The FTC's *amicus* brief is based entirely on its views of the relevant legal principles and the allegations in Zydus's antitrust counterclaims. A determination that Zydus's claims are not barred as a matter of law is not determinative of the ultimate outcome of this case. Such a holding would merely give the parties the opportunity to support their claims and defenses with evidence. While the FTC is partial in the sense of its clearly expressed interest in protecting consumers, it is not partial in the sense of expressing a view on which party should ultimately prevail in the litigation. As the Third Circuit explained, "it is not easy to envisage an *amicus* who is 'disinterested'

[15] *See, e.g.*, *Avellino*, 991 F. Supp. at 732 (granting leave for motion to file *amicus* brief because it "will aid the Court in its understanding of the issues before it").

but still has an 'interest' in the case."[16] Requiring an *amicus* to be fully impartial "became outdated long ago."[17]

III. Conclusion

For the foregoing reasons, the FTC respectfully requests that the Court grant its motion for leave to file an *amicus curiae* brief.

Dated: June 6, 2018

Respectfully submitted,

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[16] *Neonatology Assocs.*, 293 F.3d at 131 (citing Rule 29's requirement that an *amicus* must state its interest in the case).

[17] *Id.*

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FEDERAL TRADE COMMISSION'S BRIEF AS *AMICUS CURIAE*

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This case raises an important issue about the application of the *Noerr-Pennington* doctrine in the pharmaceutical industry. The *Noerr-Pennington* doctrine protects legitimate petitioning activity, including patent-infringement litigation, from antitrust scrutiny. *See United Mine Workers v. Pennington*, 381 U.S. 657 (1965). The doctrine, however, does not protect petitioning that is a "mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961); *see also Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 56 (1993) ("*PRE*"). Here, Defendant Zydus has asserted antitrust counterclaims against Takeda alleging that Takeda's patent-infringement lawsuit is a sham.[1] Takeda has argued in response that Zydus's antitrust counterclaims must fail because, among other reasons, Takeda's suit was filed under provisions of the Hatch-Waxman Act that permit brand drug manufacturers to sue generic companies for a technical act of patent infringement prior to the generic's market entry.

The Federal Trade Commission (FTC) files this brief to address Takeda's argument about the intersection of the Hatch-Waxman Act and the *Noerr-*

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[1] "Zydus" refers to Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited. "Takeda" refers to Takeda Pharmaceutical Company Limited; Takeda Pharmaceuticals USA, Inc.; and Takeda Pharmaceuticals America, Inc.

Pennington doctrine. Takeda's position incorrectly suggests that patent infringement suits brought under the provisions of the Hatch-Waxman Act can never satisfy the test for sham litigation. But the Hatch-Waxman framework does not create any special protection from antitrust liability. Such infringement suits are subject to the same case-specific inquiry that applies to any other litigation alleged to be a sham. The FTC expresses no view on any other issues raised in Takeda's Motion to Dismiss.

I. Interest of the Federal Trade Commission

The FTC, an independent federal agency charged with promoting a competitive marketplace and protecting consumer interests, exercises primary responsibility for federal antitrust enforcement in the pharmaceutical industry. The FTC has a substantial interest in the application of the *Noerr-Pennington* doctrine, including with respect to the pharmaceutical industry.[2] The FTC has substantial experience regarding the framework for generic drug approval and competition under the Hatch-Waxman Act.[3] The FTC has investigated allegations that

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[2] *See generally* FED. TRADE COMM'N STAFF, ENFORCEMENT PERSPECTIVES ON THE *NOERR-PENNINGTON* DOCTRINE (2006), *available at* https://www.ftc.gov/sites/default/files/documents/reports/ftc-staff-report-concerning-enforcement-perspectives-noerr-pennington-doctrine/p013518enfperspectnoerr-penningtondoctrine.pdf.

[3] *See generally* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002), *available at*

manufacturers of brand-name pharmaceutical products have engaged in sham petitioning, including the filing of sham Hatch-Waxman patent litigation, and has used its law enforcement authority to challenge anticompetitive Hatch-Waxman suits. *See, e.g.*, *FTC v. AbbVie Inc.*, No. 14-cv-5151, 2017 WL 4098688 (E.D. Pa. Sept. 15, 2017).

II. Relevant Regulatory Framework for Competition in the Pharmaceutical Industry

The entry of generic drugs is governed by a regulatory framework known as the Hatch-Waxman Act.[4] The Hatch-Waxman Act seeks to facilitate the introduction of lower-cost generic drugs while preserving incentives for innovation.[5] The basic contours of that framework are set forth in the Third

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https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf; FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT (August 2011), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[4] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (1984) (codified at various sections of Titles 15, 21, 28, and 35 of the U.S. Code). A separate statute not at issue in this case, the Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148 (codified at 42 U.S.C. § 201, et seq.), sets forth the approval pathway for biosimilars to biologic products.

[5] H.R. Rep. No. 98-857 (I), p. 14-17 (1984); *see also Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204 (3d Cir. 2012), *vacated, Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, 570 U.S. 913 (2013).

Circuit's opinion in *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 394-96 (3d Cir. 2015) (discussing, *inter alia*, *FTC v. Actavis Inc.*, 570 U.S. 136 (2013)). Because antitrust analysis "must always be attuned to the particular structure and circumstances of the industry at issue," *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004), we begin by explaining how certain features of the regulatory setting may be exploited by brand firms to foreclose competition in this industry.

"Hatch-Waxman 'sets forth special procedures for identifying, and resolving, related patent disputes.'" *King Drug*, 791 F.3d at 395 (quoting *Actavis*, 570 U.S. at 143). A new drug applicant must list information on any patents issued on the drug's composition or methods of use. *See* 21 U.S.C. § 355(b)(1). If the FDA approves the new drug, it publishes this information, without verification, in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (also referred to as the "Orange Book").[6] *King Drug*, 791 F.3d at 395

A generic applicant that seeks approval to market its product before expiration of a patent listed in the Orange Book must include a "paragraph IV" certification in its ANDA stating that the relevant listed patents are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C.

[6] The Orange Book is available at http://www.fda.gov/cder/ob/.

§ 355(j)(2)(A)(vii)(IV). An ANDA filer making a paragraph IV certification also must notify any patent holder "of the factual and legal basis of [the ANDA filer's] opinion . . . that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(ii), (iii), (iv)(II). *See also* 21 C.F.R. § 314.52 ("Notice of certification of invalidity, unenforceability, or noninfringement of a patent").

The Hatch-Waxman Act declares the filing of an ANDA with a paragraph IV certification to be "an act of infringement" 35 U.S.C. § 271(e)(2)(A). "'[T]he creation of a highly artificial act of infringement'—the paragraph IV certification" permits the "brand and generic to litigate patent validity" prior to the generic entering the market. *King Drug*, 791 F.3d at 396 n.8 (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990)). This feature of Hatch-Waxman also enables the generic manufacturer to litigate its challenge to the brand manufacturer's patents without having to risk liability for damages. *See* 35 U.S.C. § 271(e)(4)(C).

The patent holder "then has an incentive to sue within 45 days in order to trigger a 30-month stay of the FDA's potential approval of the generic." *King Drug*, 791 F.3d at 395-96. "If the [patent] owner brings such a suit, then approval may not be made effective until the court rules that the patent is not infringed or until the expiration of (in general) 30 months, whichever first occurs." *Eli Lilly*, 496 U.S. at 677-78 (citing 21 U.S.C. § 355(j)(4)(B)(iii)); *see also Actavis*, 570 U.S.

at 143. Nothing in Hatch-Waxman's text exempts these lawsuits from antitrust scrutiny as potential shams.

III. Patent Lawsuits Filed Pursuant to the Hatch-Waxman Framework Are Not Categorically Exempt from Being Challenged as Sham Litigation

The *Noerr-Pennington* doctrine provides that "[t]hose who petition [the] government for redress are generally immune from antitrust liability." *PRE*, 508 U.S. at 56. *Noerr-Pennington* immunity, however, is not absolute. "[A]ctivity ostensibly directed toward influencing governmental action does not qualify for [first amendment] immunity if it is a mere sham to cover an attempt to interfere directly with the business relationships of a competitor." *Id*. at 51 (quotation marks omitted). To determine whether a lawsuit is a "sham," courts apply a two-part test. "First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Id*. at 60. Second, "the court should focus on whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." *Id*. at 60-61 (internal quotation marks and citations omitted).[7]

[7] "Proof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim." *PRE*, 508 U.S. at 61.

Takeda contends that Zydus's antitrust claims necessarily fall outside the sham exception on the grounds that, *inter alia*, Zydus's filing of its ANDA with paragraph IV certifications constitutes a technical act of infringement giving rise to Takeda's unfettered right to sue and because "Zydus' paragraph IV certification and FDA regulations together allowed Takeda to have perceived some likelihood of success when it sued." Mot. at 2, 21 (quotation marks and citations omitted).[8] Neither contention is correct.

A. A Hatch-Waxman Suit Is Not Exempt From Antitrust Scrutiny as an Alleged Sham

There is no basis in the Hatch-Waxman Act's text, *Noerr* principles, or case law for singling out Hatch-Waxman suits and exempting them from being challenged as shams. Courts routinely apply *PRE*'s two-part standard to alleged sham Hatch-Waxman litigation.[9] One court recently held as a matter of law that

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[8] "Mot." refers to Takeda's Memorandum of Law in Support of Plaintiffs' Motion to Dismiss Defendants' Antitrust Counterclaims or, in the Alternative, to Bifurcate and Stay Them (Dkt. 33-1).

[9] *See, e.g.*, *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 348-49 (D.R.I. 2017); *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 361-65 (D.N.J. 2009); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 424-28 (D. Del. 2006); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 642-44 (E.D. Mich. 2000); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14-MD-02503-DJC, 2015 WL 5458570, at *11 (D. Mass. Sept. 16, 2015); *In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 1:12-MD-2343, 2013 WL 2181185, at *18 (E.D. Tenn. May 20, 2013); *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, No. CIV.A. 06-52 (GMS), 2010 WL 1485328, at *9-10 (D. Del.

two Hatch-Waxman suits asserting a patent against different generic applicants were each objectively baseless under *PRE*. *See FTC v. AbbVie Inc.*, No. 14-cv-5151, 2017 WL 4098688, at *11 (E.D. Pa. Sept. 15, 2017). The FTC is not aware of any case holding that Hatch-Waxman suits are categorically exempt from antitrust scrutiny or declining to apply the *PRE* test to the particular circumstances of the suit at issue.[10] This Court should reject Takeda's invitation to make this case the first.

Takeda's argument that a Hatch-Waxman patent suit can never be a sham lacks textual support and is premised on a misreading of the structure of Hatch-Waxman, which permits brand companies to file patent infringement litigation based on notice of an ANDA with a paragraph IV certification. The text of Section 271(e) does not exempt Hatch-Waxman suits from antitrust scrutiny as potential shams. The Supreme Court has explained that Congress created the "highly artificial act of infringement that consists of submitting [a paragraph IV] ANDA"

Apr. 13, 2010); *In re Neurontin Antitrust Litig.*, No. 02-1390, 2009 WL 2751029, at *21-23 (D.N.J. Aug. 28, 2009). The FTC offers these examples of courts' application of *PRE* to Hatch-Waxman litigation without intending to convey its agreement with the particulars of each decision.

[10] Sham litigation that is part of a series of petitioning conduct also may be scrutinized under the standards elaborated in *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162, 178-81 (3d Cir. 2015) (discussing *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508 (1972)). The FTC is not aware of any case holding that Hatch-Waxman suits are exempt from scrutiny under this standard.

because Congress had determined that certain activities reasonably related to the development and submission of an application to the FDA would not be an act of infringement. *Eli Lilly*, 496 U.S. at 678 (discussing 35 U.S.C. §§ 271(e)(1), (2)). The Hatch-Waxman "scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement." *Id*. "Thus, an act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by Section 271(e)(2)—the creation of a highly artificial act of infringement that consists of submitting an ANDA." *Id*.

Congress created this technical act of infringement for jurisdictional purposes only. It does not accord Takeda greater rights than other patent holders. "Although no traditional patent infringement has occurred until a patented product is made, used, or sold, under the Hatch-Waxman framework, the filing of an ANDA itself constitutes a technical infringement for jurisdictional purposes. But the ultimate infringement question is determined by traditional patent law principles." *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1278 (Fed. Cir. 2013) (internal citations omitted). Consistent with these principles, "the infringement inquiry called for by § 271(e)(2) is 'whether, if a particular drug were put on the market, it would infringe the relevant patent' in the usual, nonartificial sense." *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 760 (Fed.

Cir. 2016) (quotation marks and citations omitted). The Hatch-Waxman Act does not create any evidentiary presumptions, alter the burden of proof, or relieve Takeda of its obligation not to file lawsuits that are objectively baseless. Thus, while Zydus's technical act of infringement gives rise to Takeda's patent infringement suit, Takeda's suit may still be a sham.

In re Wellbutrin XL Antitrust Litigation Indirect Purchaser Class, 868 F.3d 132 (3d Cir. 2017) (discussed in Mot. at 18-19), provides no support for Takeda's argument. *Wellbutrin* does not stand for the proposition that all Hatch-Waxman suits fall outside the sham exception.[11] Like the cases discussed above, *Wellbutrin* applied *PRE* to the particular facts of the Hatch-Waxman litigation at issue. The Third Circuit merely reiterated the Supreme Court's holding "that courts can grant summary judgment on the issue of objective baselessness if 'there is no dispute over the predicate facts of the underlying legal proceeding.'" *Id.* at 151 (quoting *PRE*, 508 U.S. at 63). The fully-developed summary judgment record in *Wellbutrin*

[11] *See also In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 3967911, at *18 n.19 (E.D. Pa. Sept. 8, 2017) (denying motion to dismiss and emphasizing the "crucial fact that [*Wellbutrin*] was decided at the summary judgment stage" and affirmed "on the ground that the appellants had failed to produce evidence creating a genuine issue of material fact").

contained "nothing . . . indicating that [the patent suit plaintiffs]. . . were less than objectively reasonable." *Id*. at 149.[12]

Hatch-Waxman may "encourage" early resolution of patent disputes, but it does not encourage the filing of sham patent suits. Under certain circumstances, potentially including those Zydus alleges here, filing a patent infringement suit against an ANDA filer may amount to sham litigation under *PRE*. While the evidence ultimately may not support Zydus's Sherman Act counterclaims, the FTC respectfully submits that the Court should not adopt Takeda's argument that Hatch-Waxman suits are automatically exempt from antitrust scrutiny as potential shams.

B. The Court Should Reject Takeda's Suggestion that FDA Regulations Regarding ANDA Amendments Protect Hatch-Waxman Suits from Charges of Sham Litigation

Takeda also errs when it suggests that FDA regulations requiring new paragraph IV certifications for other than "minor" amendments to ANDAs require dismissal of Zydus's antitrust counterclaims. Takeda argues that, because FDA regulations require recertification when an amended ANDA includes "other than minor changes in a product formulation," Zydus's filing of new paragraph IV certifications with its amended ANDA "suggests that the noninfringement theory

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[12] *See also Wellbutrin*, 868 F.3d at 152 n.25 ("[I]t suffices to say that the Appellants have not provided evidence to demonstrate that it was objectively unreasonable for [the patent suit plaintiffs] to act on the technical act of infringement that the ANDA and paragraph IV certification provided.")

offered in Zydus' paragraph IV certification . . . was, or at least could be, infirm." Mot. at 21 (quotation marks and citations omitted). According to Takeda, "[t]hat possibility is all that Takeda needs to invoke *Noerr-Pennington* immunity on a motion to dismiss." *Id*.

First, Takeda's argument raises factual and legal questions that are not susceptible to resolution on a motion to dismiss. For example, the extent to which changes in Zydus's ANDA alter the applicability of the rulings in Takeda's previous lawsuit against Zydus raises questions of law and fact that cannot be resolved at this time. And, contrary to Takeda's argument, the mere "suggest[ion]" that a paragraph IV certification "could be[] infirm" does not establish that a plaintiff cannot plead facts that could support a finding of objective baselessness under *PRE*.

Second, contrary to Takeda's argument, the FDA's determination that Zydus's amended ANDA made a non-minor change to the formulation of Zydus's proposed generic product does not establish that Takeda had an objectively reasonable basis for filing its suit. FDA regulations regarding the listing and challenging of patents are agnostic as to the merits of the patents and any subsequent litigation. "[T]he FDA, acting in a purely ministerial capacity, had no role in the outcome of the Hatch-Waxman dispute resolution process." *Organon Inc. v. Mylan Pharm., Inc.*, 293 F. Supp. 2d 453, 459 (D.N.J. 2003). The FDA

itself has explained that "[a] fundamental assumption of the Hatch-Waxman Amendments is that the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents." Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36676, 36681 (June 18, 2003).

Neither the FDA regulations nor the Hatch-Waxman Act forecloses the ability of a party to allege that a Hatch-Waxman suit is a sham. The Federal Circuit may well be right when it observed that "[g]iven the presumption of patent validity and the burden on the patent challenger to prove invalidity by clear and convincing evidence, it will be a rare case in which a patentee's assertion of its patent in the face of a claim of invalidity [or noninfringement] will be so unreasonable as to support a claim that the patentee has engaged in sham litigation." *Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014). But such cases do exist. For example, in *FTC v. AbbVie Inc.*, No. 14-cv-5151, 2017 WL 4098688, at *11 (E.D. Pa. Sept. 15, 2017), the court applied *PRE* and held that the Hatch-Waxman suits at issue were objectively baseless. While the species of sham Hatch-Waxman litigations may be rare, it should not be declared extinct.

IV. Conclusion

None of the provisions of the Hatch-Waxman Act to which Takeda points establishes that Hatch-Waxman suits cannot satisfy the *PRE* test for sham litigation. "Within the maze of Hatch-Waxman, if a patent-holder's actions unlawfully maintain otherwise lawful monopoly power or use a lawful patent to manipulate the ANDA process, such actions could lead to anticompetitive effects in the relevant market." *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 532 (D.N.J. 2004). Accordingly, Hatch-Waxman suits are to be judged—just like any other lawsuit—based on case-specific application of established *Noerr-Pennington* principles.

The FTC respectfully requests that this Court reject any argument suggesting that Hatch-Waxman suits are categorically exempt from antitrust scrutiny or are presumptively objectively reasonable. The FTC would be pleased to address any questions the Court may have, including participating at any hearing, should the Court find it useful.

Dated: June 6, 2018

Respectfully submitted,

s/ *Kara L. Monahan*

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs and Counterclaim-Defendants, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants and Counterclaimants	Civil Action No. 18-1994 (FLW) (TJB) **PROPOSED ORDER GRANTING LEAVE TO FILE A BRIEF AS *AMICUS CURIAE***

Having considered the motion of the Federal Trade Commission (FTC) for leave to file a brief as *amicus curiae*; and all parties, by and through their counsel, having received due notice of the motion and having the opportunity to be heard; and for good cause shown,

IT IS on this _____ day of _____, 2018,

ORDERED that the FTC's Motion for Leave to File a Brief as *Amicus Curiae* is hereby **GRANTED**; and it is further

ORDERED that the FTC's proposed *amicus* brief is hereby deemed filed as of this date.

_____

Hon. Freda L. Wolfson
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs and Counterclaim-Defendants, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants and Counterclaimants	Civil Action No. 18-1994 (FLW) (TJB) **CERTIFICATE OF SERVICE**

I, Kara L. Monahan, an attorney with the Federal Trade Commission, hereby certify that on June 6, 2018, I caused a true and correct copy of the (1) Notice of Motion to File a Brief as *Amicus Curiae*; (2) Memorandum of Law in Support of the Motion to File a Brief as *Amicus Curiae*; (3) proposed Brief of *Amicus Curiae*; and (4) proposed Order to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification to all counsel of record.

Dated: June 6, 2018

s/ Kara L. Monahan

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