UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: ACTOS DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: All Actions	Master File No. 1:15-cv-03278-RA

DIRECT PURCHASER CLASS PLAINTIFFS' CONSOLIDATED OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

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I. INTRODUCTION

A brand company's ability to lawfully delay generic entry differs depending on whether its patent claims cover the drug product itself, or only methods of using the drug.

Under the Hatch-Waxman Act, generic companies seeking pre-expiry entry must challenge the validity or infringement of unexpired drug product claims. A brand company can then institute early infringement litigation. The FDA is barred from approving the generic for 30 months. And the brand can leverage the direct patent infringement litigation into a settlement with a compromise entry date. Drug product claims also give would-be generics a unique opportunity: If the generic is the first to challenge the product claims, it gets the coveted 180-day exclusivity for that product. When the first filer eventually launches its generic, it gets 180 days free of competition from other generic ANDA products, with all other generic approvals held up for six months.

A brand company with only method-of-use claims does not have these powers. Would-be generics are not required to challenge the validity or infringement of method-of-use claims. Instead, they may "carve out" the patented use from the proposed label and certify that they will not market their product for those uses; the FDA is then free to approve the generic. With no challenge to the use claims, the brand cannot institute an early infringement case. There is no 30-month stay. The brand has no direct infringement claim, and must wait to marshal evidence that the generic has affirmatively encouraged others to use the generic for the patented use. Even then, the remedy is enjoining the generic's inducement, not forcing its product off the market. Nor do method-of-use claims afford generics an opportunity to grab the coveted 180-day exclusivity; while a generic may challenge the use claims and get exclusivity regarding that particular use, other generics can carve the use out, get their

products on the market, and avoid the long wait of the patent challenge. The brand's opportunity to reach a favorable settlement is weak.

This action arises out of an overarching, anticompetitive scheme by brand company Takeda to unlawfully forestall generic competition and extend its $3 billion-a-year monopolies in two related drug markets – for pioglitazone hydrochloride tablets (ACTOS) and for the fixed dose combination product containing both pioglitazone hydrochloride and metformin (ACTOplus met).[1] Takeda knowingly misrepresented to the FDA that it had two patents containing product claims covering ACTOS when, in fact, it only had method-of-use claims that applied to ACTOS. By doing so, it snatched powers to delay generic entry it should not have had. And it created, for opportunistic generics, the ability to acquire a 180-day exclusivity that should not have existed.

Count 1 charges Takeda with monopolistic misconduct. Counts 4 through 6 charge that a first wave of generics – Actavis, Ranbaxy, and Mylan – with joining Takeda's exclusionary misconduct through agreements to perpetuate the undeserved 180-day exclusivity, prolonging the bottleneck 20 months (from January 2011 to August 2012) and affording Takeda billions more in sales. Count 8 charges that the last potential spoiler Teva joined the conspiracy, accepting a portion of the anticompetitive benefits from the unlawful 180-day exclusivity in exchange for its dropping a challenge to the unlawful scheme. Counts 2 and 3 charge that all the defendants engaged in an overall conspiracy.

The defendants' motions to dismiss are largely directed to a different lawsuit entirely – the end-payor case that is now on appeal. The motions raise numerous irrelevancies (mostly

[1] The direct purchaser class plaintiffs are also submitting the declaration of Brad DeMuth, which summarizes the terms of the various settlements, and Appendix A, containing four charts from the complaint detailing the impact of the unlawful scheme on ACTOS revenues and sales. Given the defendants' "confidential" designation of the settlement agreements, we are filing the Demuth declaration and accompanying exhibit under seal.

about reverse payment agreements or sham litigation) that need not be addressed here. To the extent relevant arguments are made, they lack merit.

First, the complaint alleges that Takeda violated the Hatch-Waxman reporting requirements by submitting false patent information to the FDA. At least one of the defendants concedes this.

Second, the complaint alleges that the FDA was required to rely on Takeda's misinformation, and the record evidence submitted by the defendants shows the FDA's reliance.

Third, the allegations, and the agreements submitted by the defendants, show that each of the generics joined in Takeda's exclusionary misconduct.

Finally, the argument that the direct purchasers lack causation facts is frivolous. As Teva admits, "Takeda's wrongful conduct likely will mean that there will be no generic version of Actos® available to consumers for more than 18 months after such products otherwise would be available."

II. BACKGROUND

A. Statutory and Regulatory Background

1. New drug applicants must identify patents that cover their products.

Branded drug manufacturers who wish to sell a new drug product must obtain FDA approval by filing a New Drug Application ("NDA").[2] Both the FDCA and the FDA regulations in effect from 1999 to 2002 required NDA applicants to identify the patents (1) that claim the drug or a method of using the drug *and* (2) "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the [patent] owner

[2] 21 U.S.C. § 355(a).

engaged in the manufacture, use, or sale of the drug."[3] The statute and FDA regulations required the sponsor to not only identify the patents, but also specify whether the claims in the patent covered the drug product itself (*i.e.*, drug composition or substance claims), methods of using the drug (method-of-use claims), or both.[4] In the language of the rules, the applicant was required to identify the "type" of claims in the patent that covered the drug: a "drug" (drug substance) patent, a "drug product" patent, or a "method of use" patent.[5]

2. Drug sponsors are on their honor to submit truthful patent information.

The FDA does not police the brand manufacturer's description of its patents. The agency has neither the resources nor the expertise to review patent information for its accuracy and relevance to an NDA.[6] The FDA "believes that the declaration requirements [and] . . . an applicant's potential liability if it submits an untrue statement of material fact" ensures that "accurate patent information is submitted."[7]

The FDA publishes the patent information submitted by the NDA applicant in the Orange Book.[8] The FDA's role is purely ministerial.[9]

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[3] *See* 21 U.S.C. § 355(b)(1) (emphasis added); ANDA Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,363-64 (Oct. 3, 1994) (codified as amended at 21 C.F.R. § 314.53) ("An applicant . . . shall submit information on each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it *and* with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product." (emphasis added)).

[4] 21 C.F.R. § 314.53(c)(1)(ii) (1999) & (2002); *see also* 21 C.F.R. § 314.53(b) (1999) & (2002) (describing the three patent types that can be listed in the Orange Book as drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents); 21 U.S.C. § 355(b)(1).

[5] 21 C.F.R. § 314.53(c)(1)(ii) (1999) & (2002).

[6] ANDA Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. at 50,343 ("FDA does not have the expertise to review patent information. The agency believes that its scarce resources would be better utilized in reviewing applications rather than reviewing patent claims."); *id.* at 50,345 ("FDA does not have the resources or the expertise to review patent information for its accuracy and relevant to an NDA.").

[7] *Id.* at 50,345; *see* 21 C.F.R. § 314.53(c)(2)(ii) (1999) & (2002).

[8] *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

[9] *See, e.g.*, ANDA Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. at 50,343-45; *see also* FDA/CDER Resp. Sandoz, Inc. Citizen Pet., Docket No. FDA-2009-P-0411-0010, at 9 (Mar. 15, 2010) ("FDA's role in listing patents and patent information in the Orange Book is ministerial . . . . FDA relies on the NDA sponsors to provide an accurate patent submission.").

Until 2003, there was no formal procedure for resolving listing disputes. The FDA would not change the patent information unless the brand voluntarily withdrew or amended its listed information[10]

3. The Hatch-Waxman Act is intended to get low cost generics to market sooner.

Congress enacted the Hatch-Waxman Act[11] "with the express purpose of expediting the entry of non-infringing generic competitors into pharmaceutical drug markets in order to decrease healthcare costs for consumers"[12] and sought "to make available more low cost generic drugs."[13]

Under the Act, a manufacturer seeks approval of a generic drug by filing an abbreviated new drug application (or ANDA).[14] An ANDA relies on the scientific findings of safety and effectiveness included in the brand's NDA, but must further show that the generic drug will be bioequivalent.[15]

The FDA construes its regulations to expedite generic approval and launch.[16] The FDA also prioritizes its actions in order to avoid a bottleneck and "[e]xpedite the availability of low cost, high quality generic drugs."[17]

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[10] FTC, *Generic Drug Entry Prior to Patent Expiration* 44 (July 2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf

[11] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[12] *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 378 (D. Mass. 2013) ("*Nexium I*").

[13] H.R. Rep. No. 98-857, pt. 1, at 14 (1984); *see generally New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 643-44 (2d Cir. 2015).

[14] 21 U.S.C. § 355(j)(1).

[15] 21 U.S.C. § 355(j)(2)(A).

[16] *See, e.g., Ranbaxy Labs., Ltd. v. Burwell*, 82 F. Supp. 3d 159, 198 (D.D.C. 2015) ("The FDA's interpretation . . . is entirely in keeping with . . . the larger Hatch-Waxman goal of streamlining generic drug approvals to allow safe, effective generic drugs to reach the market sooner.").

[17] *See* GDUFA Commitment Letter: Generic Drug User Fee Act Program Performance Goals and Procedures 1 (July 2012), http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf.

4. Hatch-Waxman Act allows for generic entry even in the face of a brand company's patents.

The patent information submitted for the brand (*i.e.*, the reference listed drug, or RLD) serves as an ANDA's frame of reference.[18] Hatch-Waxman outlines two routes, depending on the brand's claim characterization, for a generic to enter the market in the face of the brand's patents on the RLD: (1) "paragraph IV certifications"[19] and (2) "section viii statements."[20]

a. Paragraph IV certifications.

A generic must provide a "certification" with respect to each patent identified in the Orange Book "which claims the [RLD] or which claims a use for [that] drug for which the applicant is seeking approval."[21] If the generic wishes to remain out of the market until expiration of the identified patent, a generic can certify to that effect.[22] But if the generic wants FDA approval earlier than the expiration of a patent that contains claims that cover the drug product, the generic must certify that the brand's patent is invalid or not infringed by its ANDA – a so-called "paragraph IV certification."[23]

"The patent statute treats such a filing [under paragraph IV] as itself an act of infringement, which gives the brand an immediate right to sue."[24] A suit triggers an automatic stay of the FDA's ANDA approval for 30 months – functionally, an automatic preliminary injunction.[25] Until the 30 months pass or a court issues a decision that the patent is invalid or not infringed by the generic's ANDA, the FDA may grant "tentative approval," but cannot

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[18] *Teva Pharm., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008)

[19] 21 U.S.C. § 355(j)(2)(A)(vii)(IV),

[20] 21 U.S.C. § 355(s)(A)(viii); *see also Caraco*, 132 S. Ct. at 1676-78.

[21] 21 U.S.C. § 355(j)(2)(A)(vii).

[22] 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(III).

[23] 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see Caraco*, 132 S. Ct. at 1677.

[24] *Caraco*, 132 S. Ct. at 1677 (citing 35 U.S.C. § 271(e)(2)(A)).

[25] 21 U.S.C. § 355(j)(5)(B)(iii).

grant the "final approval."[26] But after 30 months pass, the FDA may approve the ANDA and the generic can launch. If the brand manufacturer's suit is still ongoing by the time of FDA approval and launch, the generic is said to launch "at risk."[27]

The Act also provides first filers of an ANDA containing a paragraph IV certification with a 180-day "exclusivity period." The FDA will not approve a later-filed ANDA for at least 180 days after either (i) a court decision finding the patent invalid or not infringed, or (ii) the first commercial marketing of the drug under the first ANDA, whichever is earlier.[28] This period "can prove valuable, possibly worth several hundred million dollars."[29] This 180-day exclusivity creates a "bottleneck" that delays approval of *all* other generic applicants.

b. Section viii statements allow generic companies to come to market with labels "carving out" patented methods of using the drug.

A second route to ANDA approval exists when the NDA applicant has submitted patent information identifying claims for methods of using the drug.[30] In that case, the ANDA applicant may choose not seek approval of its drug for the ostensibly patented use, known as a "section viii statement."[31] A section viii statement is commonly used when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug. If an ANDA applicant files a section viii statement, the patent

[26] *See id.* The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay or any remaining patent or regulatory exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA).

[27] *See* Grace Lillian Wang, *Teva v. Eisai: What's the Real "Controversy"?*, 66 Food & Drug L.J. 631, 638 n.46 (2011).

[28] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

[29] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) (internal quotations omitted).

[30] *Caraco*, 132 S. Ct. at 1676-78.

[31] 21 U.S.C. § 355(j)(2)(A)(viii).

claiming the protected method of use will not serve as a barrier to ANDA approval, and if the ANDA is otherwise approvable, the FDA may approve the ANDA.[32]

Where the patent claims only methods of using the applicable drug, an ANDA applicant must choose either (i) to pursue a paragraph IV challenge to that patented use, or (ii) carve-out the ostensibly patented use from its proposed label, and provide a section viii statement.[33] Where the proposed labeling carves out the patented use, *only* a section viii statement is acceptable.[34] Where a patent has claims for the drug product (or substance) and methods of using it, the generic may split its certification (to paragraph IV as to the product claims, and section viii as to the use claims).[35]

If an ANDA applicant makes only a section viii statement, then the patentee or NDA holder *cannot* obtain an automatic 30-month stay on generic competition. And the generic filer cannot get a 180-day exclusivity for the drug. The FDA remains free to approve other ANDA applicants with section viii statements, regardless whether the first filer has come to market or not. In short, when the patent is reported to have only use claims that apply to the product,

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[32] *Caraco*, 132 S. Ct. at 1676-77; *see also* H.R. Rep. No. 98-857, pt. 1, at 21 (1984) ("The [ANDA] applicant need not seek approval for all of the indications for which the listed drug has been approved. For example, if the listed drug has been approved for hypertension and angina pectoris, and if the indication for hypertension is protected by patent, then the applicant could seek approval for only the angina pectoris indication.").

[33] *Id.*

[34] ANDA Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. at 50,347 ("[I]f a patent claims a method of using the listed drug, and labeling for the ANDA applicant's proposed drug product does not contain any indications covered by the method of use patent, the ANDA applicant should not submit a [paragraph IV] certification . . . for such a patent."); *see Watson Labs., Inc. v. Sebelius*, No. 12-1344, 2012 WL 6968224, at *6 (D.D.C. Oct. 22, 2012) ("According to FDA, the FDCA prohibits an ANDA applicant from filing a paragraph IV certification challenging a patent for a use that it has carved out from its proposed labeling. Rather, an applicant must file section viii statements for a proposed carve-out of labeling referring to a patented method of use." (internal citations omitted)), *vacated as moot*, 2013 WL 11250319 (D.C. Cir. June 10, 2013).

[35] ANDA Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. at 50,347 ("If, however, there are listed patents that present both a product and method of use claim, the applicant may file a paragraph IV certification with respect to the product patent or patent claim and a statement that the product that is the subject of the application does not involve a patented method of use with respect to the method of use patent or patent claim.").

there is no potential for a regulatory bottleneck for the approval of generics that carve-out the ostensibly patented use.

When a patent contains multiple types of claims, an ANDA applicant may file a paragraph IV certification to some claims and a section viii statement as to use claims.[36] The FDA's position is that a paragraph IV certification and a section viii statement "are not overlapping, and an applicant does not have the option of making a [paragraph IV] certification in lieu of, or in addition to, a [section viii] statement."[37] So when a patent holder identifies a patent as claiming both a drug product and a method of use, and an ANDA applicant chooses to submit a section viii statement with respect to any method-of-use claims, the ANDA applicant must also submit a paragraph I, II, III, or IV certification for any product claims.[38]

5. The consequences of submitting false patent information.

Important regulatory and competitive consequences flow from the distinction between patents described as containing relevant drug product claims and patents described as containing only method-of-use claims. As the Supreme Court recognizes,

> [The Hatch Waxman] Amendments instruct the FDA (assuming other requirements are met) to approve an ANDA filed with a section viii statement when it proposes to market a drug for only unpatented methods of use. To fulfill that charge, the FDA must determine whether any patent covers a particular method of use; and to do that, the agency (which views itself as lacking expertise in patent matters) relies on the [patent information] submitted in the regulatory process. [Inaccurate patent information]

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[36] The FDA has a consistent practice of permitting ANDA applicants to submit applications containing both a paragraph IV certification and a section viii statement for the same patent. *See, e.g.*, FDA/CDER Resp. Sandoz, Inc. Citizen Pet., Docket No. FDA-2009-P-0411-0010 (Mar. 15, 2010); FDA/CDER Resp. Novo Nordisk, Inc. Citizen Pet., Docket No. FDA-2008-P-0343-0009 (Dec. 4, 2008); FDA/CDER Resp. Caraco Pharms. Labs., Ltd. Citizen Pet., Docket No. FDA-2008-P-0411-0006 (Dec. 4, 2008).

[37] *See* ANDA Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. at 50,347.

[38] *See, e.g.*, FDA/CDER Resp. Sandoz, Inc. Citizen Pet. at 7-8, Docket No. FDA-2009-P-0411-0010 (Mar. 15, 2010); FDA/CDER Resp. Novo Nordisk, Inc. Citizen Pet. at 10, Docket No. FDA-2008-P-0343-0009 (Dec. 4, 2008).

> therefore throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates.[39]

If, for example, a brand company misidentifies a patent whose only relevant claims are method of use claims as containing *both* method of use claims *and* product claims covering the drug, the improper identification results in the following consequences:

1. Any generic company seeking to market a generic version of the RLD must make a paragraph IV certification to the product claims allegedly covering the RLD even if it is carving out the ostensibly patented uses from its label;

2. The brand company will get notice of the paragraph IV certification, alerting it to incoming generic competition and identifying the specific generic company (or companies) that are seeking to enter the market;

3. The paragraph IV certification will act as a technical act of patent infringement, allowing the brand company to commence infringement litigation against the generic;

4. The filing of the infringement action will bar the FDA from approving the generic's ANDA for 30 months (or until the litigation is resolved, whichever is sooner); and

5. If the generic company is a "first filer", the generic will receive 180 days of market exclusivity, delaying all generic competition until those 180 days have passed or the courts have ruled the product claims are invalid or not infringed.

None of this happens if the brand company properly identifies the patent as only containing claims covering methods of using the RLD.

6. The FTC finds brands improperly submitting patents as drug product patents to delay the onset of generic competition.

In the 1990s, some brand-name manufacturers submitted patent information inappropriate for listing in the Orange Book.[40] The ensuing litigation prevented or delayed the FDA's approval of ANDAs. In 2002, the FDA initiated rulemaking to ameliorate this

[39] *Caraco*, 132 S. Ct. at 1684 (internal citation omitted); *see also id.* at 1688 (recognizing the FDA's "statutory duty to approve generic drugs that do not infringe patent rights"). *Caraco* involved use codes, a specific type of patent information that must be provided under the Act.

[40] *See* FTC Generic Drug Study at 39-56 & A-39 to A-45 (discussing Orange Book listing issues and describing several such instances).

situation[41] and adopted a final rule effective August 18, 2003.[42] The 2003 rule therefore "require[d] the NDA applicant or holder to identify specifically the approved uses claimed by the method-of-use patent," thereby enabling ANDA applicants and the FDA to "determine whether the [ANDA] applicant must submit a patent certification or may submit a section viii statement."[43] The agency acknowledged, though, that even its new system would ultimately depend on the accuracy of information submitted by NDA applicants.[44]

Congress complemented the FDA's rulemaking by authorizing generic manufacturers in patent infringement suits to assert a legal counterclaim challenging the brand manufacturer's submission of patent information to the FDA.[45]

B. Facts.

1. Takeda's patents.

In August 1987, the United States Patent and Trade Office ("PTO") issued U.S. Patent No. 4,687,777, containing claims for pioglitazone, the active pharmaceutical ingredient in ACTOS.[46]

In January 1999, Takeda submitted an NDA seeking approval to manufacture, market, and sell ACTOS. Six months later, in July 1999, the FDA approved the NDA for the use of ACTOS to improve glycemic control in adults with Type 2 diabetes – either as monotherapy or

[41] Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of ANDAs Certifying That a Patent Claiming a Drug is Invalid or Will Not Be Infringed, 67 Fed. Reg. 65,448 (proposed Oct. 24, 2008).

[42] Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of ANDAs Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676 (June 18, 2003).

[43] *Id.*; *see id.* at 36,685 ("The specific method-of-use claims are essential to our review [of section viii statements].").

[44] *See, e.g., id.* at 36,687 ("[W]e will not evaluate a patent to assess whether the declaration is accurate or whether the patent has been appropriately submitted for listing."); *id.* at 36,682 ("In determining whether an ANDA applicant can 'carve out' the method of use, . . . we will rely on the description of the approved use provided by the NDA holder or patent owner.").

[45] *See* 21 U.S.C. §§ 355(j)(5)(C)(ii), 1101(a)(2)(C).

[46] Second Consol. Am. Class Action Compl. & Jury Demand ("Compl.") ¶ 158, Jan. 8, 2016, ECF No. 55.

in combination with a sulfonylurea, metformin, or insulin.[47] The '777 patent would expire on January 17, 2011.[48]

At some point in 1999, Takeda submitted to the FDA information about the '777 patent, and the next year it appeared in the Orange Book with a new chemical entity identification.

In October 1999, the PTO issued U.S. Patent No. 5,965,584. The '584 patent has two types of claims, (1) those for a pharmaceutical composition comprising pioglitazone or salts thereof *in combination with* a biguanide (*e.g.*, metformin), and (2) those for methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof *in combination with* a biguanide (*e.g.*, metformin).[49] The '584 patent expires on June 19, 2016.[50] The product claims (first set) do not cover the ACTOS product itself. The use claims (second set) only cover the specified method of using ACTOS. The '584 patent expires on June 19, 2016.[51]

On November 5, 1999, Takeda submitted patent information to the FDA. Takeda told the FDA that the '584 patent claimed both the "[d]rug product" ACTOS and its "method of use."[52] That was false.

In December 2001, the PTO issued U.S. Patent No. 6,329,404.[53] The '404 patent also has two types of claims, (1) those for a pharmaceutical composition comprising pioglitazone or salts thereof *in combination with* an insulin secretion enhancer (*e.g.*, a sulfonylurea, such as

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[47] Compl. ¶¶ 159-60.

[48] Compl. ¶158.

[49] Compl. ¶ 166.

[50] *Id.*

[51] *Id.*

[52] Compl. ¶ 170; *see* Ex. 9 to Decl. of Adam R. Lawton 7-8, ECF No. 66-4; *see also* FDA/CDER Resp. Sandoz, Inc. Citizen Pet. At 1-2, Docket No. FDA-2009-P-0411-0010 (Mar. 15, 2010) ("When submitted, Takeda's patent declarations for the '584 and '404 patents each stated that the patents claimed *both the drug product and a method of use.*") (emphasis added).

[53] Compl. ¶ 172.

glimepiride), and (2) those for methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with an insulin secretion enhancer.[54] The product claims (first set) do not cover the ACTOS product itself. The use claims (second set) only covers the specified method of using ACTOS. The '404 patent also expires on June 19, 2016.[55]

On January 3, 2002, Takeda submitted patent information to the FDA. Takeda told the FDA that the '404 patent claimed both the "[d]rug [p]roduct" ACTOS and its "[m]ethod of [u]se."[56] That also was false.

Takeda submitted eight other patents to the FDA that, it reported, contained only method-of-use claims covering ACTOS.[57]

2. The first wave of generics files ANDAs.

On July 15, 2003 – the first day generics could do so – defendants Actavis, Mylan, and Ranbaxy (the "first wave generics") filed ANDAs seeking FDA approval to manufacture, market, and sell generic ACTOS.[58]

The Mylan ANDA carved-out the use of ACTOS in combination with other agents; it contained a paragraph IV certification as to the '777 ACTOS compound patent, split certifications to the combo patents (paragraph IV as to product claims, section viii statements

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[54] *Id.*

[55] *Id.*

[56] Compl. ¶ 176; *see* Ex. 9 to Decl. of Adam R. Lawton, ECF No. 66-4, at 9-10; *see also* FDA/CDER Resp. Sandoz, Inc. Citizen Pet., Docket No. FDA-2009-P-0411-0010 (Mar. 15, 2010).

[57] Compl. ¶ 178.

[58] Compl. ¶ 189.

as to use claims), and section viii statements as to the other ACTOS patents.[59] On November 3, 2004, the FDA granted tentative approval for Mylan's ANDA.[60]

As accepted for filing by the FDA, the Actavis ANDA carved-out the use of ACTOS in combination with other agents; it contained a Paragraph III certification as to the '777 ACTOS compound patent, split certifications to the combo patents (paragraph IV as to product claims, section viii statements as to use claims), and section viii statements as to the other ACTOS patents.[61] On December 13, 2005, the FDA granted tentative approval for Actavis's ANDA.[62]

The Ranbaxy ANDA also contained a paragraph III certification as to the '777 Patent, split certifications tot eh combo patents (paragraph IV as to product claims, section viii statements as to use claims), and section viii statements as to the other ACTOS patents.[63]

In each case, the split certifications indicate that Mylan, Actavis, and Ranbaxy knew or had reason to believe that section viii statements alone were insufficient to address the patent information that had been filed by Takeda regarding the '584 and '404 patents. (Actavis

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[59] Compl. ¶ 191; *see Sebelius*, 2012 WL 6968224, at *7, *10.

[60] *See* http://1.usa.gov/1SbVqJo (FDA Approval History for Mylan ANDA 076801); *see also* Mylan's Pretrial Br., *Takeda Chem. Indus. v. Mylan Labs., Inc.*, No. 03-cv-8253, 2005 U.S. Dist. Ct. Motions LEXIS 27367, at *33-*34 (S.D.N.Y. Dec. 2, 2005) (noting that "FDA has 'tentatively' approved Mylan's ANDA and therefore has found the proposed labeling of Mylan's Package Outsert acceptable, which excludes any reference or suggestion to use the Mylan products for the combination therapies covered by Takeda's Orange Book-listed patents for the ACTOS® products.")

[61] Compl. ¶ 193. As originally filed, Actavis's ANDA included only paragraph IV certifications for the method-of-use patents. In August 2003, Actavis "amended its ANDA to change its certifications to the [method-of-use patents] to Section viii statements, while maintaining its Paragraph IV certifications as to the composition claims" of the combo patents. *Sebelius*, 2012 WL 6968224, at *6, *11. Actavis's proposed labeling also revised the reference to combination therapy contained in the ACTOS label. "Among other things, [Actavis] change[d] the direction in the Actos label that read 'for patients not responding adequately to monotherapy, *combination therapy*' should be considered" to '[f]or patients not responding adequately to monotherapy, *other therapy* should be considered.'" *Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc.*, 329 F. Supp. 2d. 394, 399 (S.D.N.Y. June 10, 2004).

[62] *Sebelius*, 2012 WL 6968224, at *6 , *11.

[63] Compl. ¶ 195; *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 417 F. Supp. 2d 341, 366 & n.28 (S.D.N.Y. 2006) (Ranbaxy "filed paragraph IV certifications relating to the composition claims" and "included . . . Section viii Statements with respect to the method claims" of the combo patents).

learned this directly from the FDA; its application was at first rejected until corrected to reflect a split certification, with the FDA explaining to it the need to do so).[64]

By filing paragraph IV certifications, each first filer acquired a right that it would not have had in the absence of Takeda's wrongful description of those patents as covering the ACTOS product – the right to be treated as "first-to-file" ANDA applicants entitled to enjoy 180-day exclusivity from other generic company ANDA-approved sales, and the ability to bottleneck the entry of other generics (subject to certain exceptions) until such time as one of these first wave generics chose to launch its product.[65]

The FDA ultimately concluded that Mylan, Ranbaxy, and Actavis were entitled to "shared" 180-day exclusivity with respect to generic ACTOS; each had first-to-file exclusivity (subject to exceptions) from non-first wave generics for the first six months from when the first of any one of the first wave generics chose to launch their generic product (assuming the company had final approval from the FDA, of course).[66] This status was only available under the combo patents by reason of Takeda's false description of those patents as claiming the ACTOS product.[67]

After receiving the first filers' paragraph IV certifications, Takeda initiated patent infringement suits against each of the first wave generics.[68] In each case (the complaints are more or less identical), Takeda alleged "upon information and belief" (i) counts under 35 USC § 271(e)(2)(A) that conduct by Ranbaxy, Mylan, and Actavis would induce infringement of claims

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[64] *Sebelius*, 2012 WL 6968224, at *6, *11.

[65] Compl. ¶ 197.

[66] *Id.*

[67] *Id.*

[68] Compl. ¶ 198. In addition, Takeda filed nearly identical complaints against each of the first wave generics in other districts. *See* Compl., *Takeda Chem. Indus., Ltd. v. Mylan Labs. Inc.*, No. 03 1608, 2003 WL 25593100 (W.D. Pa. Oct. 23, 2003); Compl., *Takeda Chem. Indus., Ltd. v. Watson Pharm., Inc.*, No. 03-cv-01335 (D. Nev. Oct. 23, 2003); Compl., *Takeda Chem. Indus., Ltd. v. Ranbaxy Labs., Ltd.*, No. 03-5055, 2003 WL 25816442 (D.N.J. Oct. 23, 2003).

of the combo patents, and (ii) counts under 35 USC § 271(b) that conduct by each of the first wave generics would induce infringement of the method-of-use claims in the combo patents and some of the other ACTOS patents.[69] Takeda brought no claims against the first wave generics alleging that the proposed generic products would directly infringe the product claims in the '584 or '404 patents. None of the complaints specified any actual acts of induced infringement of those patents, instead relying on speculation as to what the generics might do in the future.[70]

3. Teva files its generic ACTOS ANDA.

On July 14, 2004, Teva filed an ANDA for approval of its generic ACTOS.[71] The Teva ANDA contained a paragraph III certification as to the '777 patent. But unlike the first wave generics' ANDAs, Teva's did not contain a paragraph IV certification with respect to either of the combo patents;[72] as to those, Teva included only section viii statements.[73] The section viii statements asserted that Teva's label would "carve out" information regarding methods of using ACTOS in combination with a biguanide or an insulin secretion enhancer (the methods of use claimed by the combo patents).[74]

Teva's decision not to include a paragraph IV certification with respect to the combo patents reflects a strategy to have the FDA approve Teva's ANDA without regard to whether

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[69] *Mylan* Compl. ¶¶ 46-65 (§ 271(e)(2)(A) claims), 66-137 (§ 271(b) claims); Compl., *Takeda Chem. Indus., Ltd. v. Watson Pharma., Inc.*, No. 03CV08254, 2006 WL 6810286 (S.D.N.Y. Oct. 17, 2003) ("*Actavis* Complaint"), ¶¶ 34-58 (§ 271(e)(2)(A) claims), 59-112 (§ 271(b) claims); *Ranbaxy* Compl. ¶¶ 32-60 (§ 271(e)(2)(A) claims), 61-138 (§ 271(b) claims); *see also* Am. Compl., *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 03-cv-8253, 2004 U.S. Dist. Ct. Pleadings LEXIS 7874 (S.D.N.Y. Sept. 29, 2004) ("Am. *Mylan* Compl."), ¶¶ 46-65 (§ 271(e)(2)(A) claims), 66-136 (§ 271(b) claims).

[70] *See, e.g.*, Am. *Mylan* Compl. ¶¶ 52-53 ("Upon information and belief, Mylan's generic marketing practices include listing generic products on its website and referring consumers to a corresponding brand name product. Upon information and belief, Mylan intends to do the same for any approved generic pioglitazone . . . Upon information and belief, Mylan has planned and intended to actively induce others to infringe the '584 patent when their ANDA application is approved and plans and intends to do so on approval."); *Actavis* Compl. ¶¶ 45-46 (same, as to Actavis).

[71] Compl. ¶ 204.

[72] Compl. ¶ 205.

[73] *Id.*

[74] *Id.*

any other ANDA applicant was otherwise entitled to a 180-day exclusivity period with respect to ACTOS.[75] This leap frog strategy would occur in one of two ways: either the FDA would determine (without court proceedings) that the section viii statement was sufficient (and not give credence to the product listing as to ACTOS in some way), or (if the FDA were unwilling to do so), a court would determine the listing incorrect and require correction under § 355(j)(5)(C)(ii).[76] Under either path, the FDA approval of Teva's ANDA would not be delayed by any 180-day exclusivity for another generic ACTOS product.[77] Teva sought to leap frog over the first wave generics – Mylan, Ranbaxy, and Actavis – and launch a generic version of ACTOS once the '777 patent expired in January 2011.[78]

In or about February 2006, Teva received tentative approval from the FDA for its ACTOS ANDA.[79] By doing so, the FDA accepted Teva's section viii statement and carved-out labeling of the methods of using ACTOS with metformin and insulin. Takeda did not sue Teva for patent infringement for its ACTOS ANDA until May 2009, when it also sued Teva for infringement for Teva's ACTO*plus* met ANDA.[80]

4. The challenge to the '777 patent is tried.

The Takeda actions against Mylan, Ranbaxy and Actavis were consolidated, and the court opted to try Mylan's challenge to the '777 patent first.[81] After a 2006 bench trial, the

[75] Compl. ¶ 206.

[76] *Id.*

[77] *Id.*

[78] Compl. ¶ 207.

[79] *See* Mem. Supp. Teva's Mot. Add Counterclaim 5, *Takeda Pharm. Co. Ltd. v. Teva Pharm. Indus. Ltd.*, No. 09-cv-4665 (S.D.N.Y Mar. 30, 2010), ECF No. 49 ("On February 7, 2006, the FDA granted tentative approval to Teva's ANDA.").

[80] Compl. ¶ 224.

[81] Compl. ¶ 210.

court found that the '777 patent valid and infringed.[82] In June of 2007 the Federal Circuit affirmed.[83]

The decision on the '777 patent had no bearing on the merits of Takeda's induced infringement claims based on the combo patents, nor did it have any bearing on whether Takeda had submitted false information to the FDA regarding those patents.[84]

5. Takeda sues Mylan and Teva for their ACTO*plus* met ANDAs.

On August 29, 2005, the FDA approved Takeda's NDA for ACTO*plus* met, which combined two active ingredients, pioglitazone hydrochloride and metformin hydrochloride.[85] Takeda listed the '584 patent in the Orange Book as a drug product patent for ACTO*plus* met and listed three additional patents as applicable method-of-use patents.[86]

On or about March 5, 2008, Mylan submitted an ANDA seeking FDA approval to market a generic ACTO*plus* met (entitling Mylan, as the first filer, to 180 days of exclusivity), and made a paragraph IV certification to each relevant patent.[87] On August 5, 2008, Takeda sued Mylan.[88]

In late 2008 or early 2009, Teva submitted an ANDA for generic ACTO*plus* met.[89] Takeda sued.[90] Takeda asserted that Teva's ACTOS ANDA and its ACTO*plus* met ANDA induced infringement of the use claims in the combo patents.[91]

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[82] Compl. ¶ 211.

[83] *Id.*

[84] Compl. ¶ 212.

[85] Compl. ¶¶ 214–15.

[86] *Id.*

[87] Compl. ¶ 217.

[88] Compl. ¶ 219.

[89] Compl. ¶ 222.

[90] Compl. ¶ 224.

[91] *Id.*

6. In 2009 and 2010, Takeda reiterates the false characterization of the '584 and '404 patents.

In August 2009, presumably recognizing that Teva's leap frog may be successful, another generic manufacturer (Sandoz) filed a petition requesting that the FDA refrain from granting final approval for any ACTOS ANDA that did not contain paragraph IV certifications to the '584 and '404 patents.[92]

In November 2009, Takeda wrote the FDA to "confirm the listing" of the combo patents "under the terms . . . [of the] original submissions."[93] It noted a "section viii statement alone is insufficient when a listed patent includes claims *other* than a method-of-use claims."[94] Takeda demanded that the FDA require all ANDA applicants for generic ACTOS submit a certification and not a section viii statement.[95]

On January 22, 2010, in a comment to the petition, Takeda again stated that it "characterized [the combo patents] for FDA in the appropriate patent declarations as containing both 'Drug product' and 'Method of use' claims," and confirmed that "[s]ince the original submission of these patents to FDA, Takeda has continued to certify to the applicability of the patents to Actos® under the original declarations . . . ."[96] Takeda reiterated to the FDA that, as a result, "a statement under 'section viii' . . . for each patent is, by itself, legally insufficient."[97]

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[92] Compl. ¶ 232; *see* Sandoz, Inc. Citizen Pet., Docket No. FDA-2009-P-0411-0001 (August 25, 2009).

[93] *See* Ex. 9 to Decl. of Adam R. Lawton, ECF No. 66-4, at 4.

[94] *Id.*

[95] *Id.* at 6.

[96] Compl. ¶ 232; *see* Ex. 9 to Decl. of Adam R. Lawton, ECF No. 66-4, at 2.

[97] *Id.*

7. Takeda negotiates the March 2010 pact with Mylan, Actavis, and Ranbaxy.

By early 2010, the FDA was poised to grant final approval to the Mylan and Actavis ANDAs in late January 2011. The FDA had granted tentative approval to Mylan's and Actavis's ANDAs years earlier; this meant the only remaining requirement for final approval was resolution of patent stay requirements. But the '777 patent would expire on January 17, 2011, and the 30-month stay from the combo patent certifications had long expired. Takeda and the generics faced a trial in June on Takeda's allegations the generics might affirmatively engage in acts to induce infringement of the use claims in the combo patents. But the first wave generics had formally carved out those uses from their proposed FDA labels, and the FDA had accepted them. The generics denied any plans to induce infringement. And even in the unlikely event Takeda prevailed, the remedy for induced infringement would be to enjoin inducing conduct, not bar entry of the product.

As things stood, Mylan and Actavis would each gain final approval in late January 2011 and launch generic ACTOS.[98] If they could preserve the falsely-created 180-day exclusivity, they would reap supracompetitive sales.

But Teva remained in the likely spoiler role. Teva was pursuing its section viii statement strategy. Once successful, Teva (who also had tentative approval) could also launch its generic in January 2011, as could any other ANDA filers (such as Sandoz, Torrent, Aurobindo, and others) whose applications became complete and had similar section viii carve-outs. The 180-day exclusivity, and the potential to bottleneck other generics, would be lost.[99]

In mid-March 2010, Takeda orchestrated a group deal in which all three of the first wave generics – Mylan, Actavis, and Ranbaxy – reached an overall agreement memorialized in

[98] Compl. ¶ 239; *cf. id.* ¶ 352.

[99] Comp. ¶ 247.

documents with nearly identical terms (the "March 2010 pact").[100] Takeda and the first wave generics agreed to two common, unlawful goals: (i) preserving and prolonging the falsely created 180-day exclusivity for ACTOS, and (ii) delaying entry of generic ACTOS products.

Takeda received identical commitments from each generic to delay entry of generic ACTOS until August 17, 2012 (20 months after the January 17, 2011 date), with similar delay commitments for ACTO*plus* met.[101] The first wave generics understood that their agreement to delay would bottleneck other generic entrants for six months after the delayed launch of generic ACTOS.

For the first wave generics, and in exchange for the delay, the March 2010 pact was structured to maximize the likelihood that the first wave generics would keep their undeserved 180-day exclusivity. The agreements contained coordinated launch provisions designed to dissuade Teva's (or any other generic's) efforts to challenge exclusivities and gain early entry.[102] The March 2010 pact secured coordinated launch *amongst several generics* – the multiple threat was a further disincentive to Teva's continuing the section viii leapfrog. First, Mylan, Actavis, and Ranbaxy agreed to maintain their paragraph IV certifications as to the falsely described product claims of the '584 and '404 patents; they agreed to treat Takeda's false patent information as truthful, and never challenge it.[103] Second, the first wave generics agreed to amend their ANDAs to change their section viii statements on all ACTOS patents (including the combo patents) to paragraph IV certifications and to *no longer* carve out the protected uses from its labeling; doing so gave them a hassle-free, non-carved-out label, an arguable advantage

[100] Compl. ¶ 248.

[101] Compl. ¶ 250.

[102] Compl. ¶¶ 257-58.

[103] *See* Ex. 1 to Kokkines Decl. (Ranbaxy Agreement), Sections 2.4, 2.5; Ex. 2 to Kokkines Decl. (Mylan ACTOS Agreement), Sections 2.4, 2.5; Ex. 4 to Kokkines Decl. (Watson Agreement), Sections 2.4, 2.5.

over Teva and their other competitors.[104] Third, the first wave generics agreed to permit Takeda to negotiate a later deal with Teva in which Teva would be allowed to join in the fruits of the falsely created 180-day exclusivity.[105] Finally, as further sweeteners to Ranbaxy and Actavis, Takeda agreed to provide them both higher-than-market side deals in which Takeda granted them licenses to market *another drug for which they had never filed an ANDA*, generic ACTO*plus* met.[106]

The settlements were announced within days of each other (March 10, 15, and 16),[107] using nearly identical language.[108] The entry dates for all products were identical.[109] The conditions of entry were identical, with the language for the coordinated entry dates nearly identical for all three.[110] The terms of the agreements were to be confidential, yet each agreement permitted Takeda to share the otherwise secret coordinated launch provisions with other generic competitors.[111]

Up until March of 2010, the first wave generics had acted unilaterally, in their respective self-interests. But by entering into the March 2010 pact, these generics exacerbated the consequences of Takeda's false submissions to the FDA by rejiggering their patent certifications and prolonging the bottleneck preventing generic entry.[112]

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[104] *See* Ex. 1 to Kokkines Decl. (Ranbaxy Agreement), Section 2.4; Ex. 2 to Kokkines Decl. (Mylan ACTOS Agreement), Section 2.4; Ex. 4 to Kokkines Decl. (Watson Agreement), Section 2.4.

[105] *See* Ex. 1 to Kokkines Decl. (Ranbaxy Agreement), Section 3.1; Ex. 2 to Kokkines Decl. (Mylan ACTOS Agreement), Section 3.1; Ex. 4 to Kokkines Decl. (Watson Agreement), Section 3.1; *see also* Compl. ¶ 299.

[106] Compl. ¶¶ 272-74.

[107] Compl. ¶ 252.

[108] *Id.*

[109] *Id.*

[110] *Id.*

[111] *Id.*

[112] Compl. ¶¶ 259, 268.

8. Teva asserts a counterclaim to correct the false patent information for the '584 and '404 patents.

On March 15, 2010, the FDA granted Sandoz's petition, noting that the FDA relies "solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents."[113] The FDA noted that Takeda's original patent information for ACTOS had indeed "stated that the patents claimed both the drug product and a method of use."[114] As a result, ACTOS ANDAs could not gain approval through a section viii statement to the combo patents; an ANDA applicant seeking pre-expiry entry was required to submit a paragraph IV certification.

On March 30, 2010, Teva moved to add a counterclaim to "correct or delete the misleading and/or incorrect information [Takeda] submitted to the FDA concerning the scope of the drug product claims in the '584 and '404 patents in relation to the Actos® NDA."[115] The corrected information "would show that the drug product claims in the '584 and '404 patents do *not* cover Actos®," and that would mean "there is no basis for requiring Teva to submit a paragraph IV certification to those claims in connection with Teva's Actos® ANDA."[116] As a result, the FDA would be free to approve Teva's ANDA "after . . . the '777 patent . . . expires in January 2011."[117] Teva saw Takeda's submissions as false: "The information submitted by Takeda was false, misleading, and/or incorrect in that it stated or strongly implied that the

[113] Compl. ¶ 234.

[114] *Id.*

[115] Teva Mem. Support Mot. Add Counterclaim 2; *see* Compl. ¶¶ 282-83, 285.

[116] Teva Mem. Support Mot. Add Counterclaim 2-3; *see also id.* at 2 ("Simply put, the drug product claims in those patents do not cover the Actos® drug product, and therefore those claims cannot properly be listed for the Actos® NDA.").

[117] *Id.* at 3.

drug product claims in those two patents cover the Actos® drug product, when in fact they unequivocally do not.[118]

Teva argued that the consequence of Takeda's false filings was generic delay. As "a direct result of Takeda's submissions, the FDA now states that Teva must submit paragraph IV certifications to those claims as part of its ANDA for a generic version of Actos®. The inevitable effect of this change will be to substantially and impermissibly delay FDA approval for Teva's ANDA."[119] Teva continued,

> Teva will be substantially harmed unless Takeda is required to correct or delete the patent information concerning the drug product claims of the '584 patent and the '404 patent in the Orange Book in relation to the Actos® NDA. The consequence of those incorrect listings – and the resulting directive by the FDA that ANDA applicants must file paragraph IV certifications – will likely cause a substantial delay of approximately *two years* in FDA approval of Teva's ANDA, from January 2011 to February 2013. In addition, Takeda's wrongful conduct likely will mean that there will be *no* generic version of Actos® available to consumers for more than 18 months after such products otherwise would be available. By contrast, if Takeda were required to correct or delete the information it previously submitted to the FDA, none of these improper delays would occur, and ANDAs for generic versions of Actos® could be approved in the manner and within the time-frames that Hatch-Waxman actually contemplates.[120]

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[118] *Id.* at 1; *see also id.* at 1 n.1 ("Teva does not challenge Takeda's listing of the method-of-use claims (as opposed to the drug product composition claims) of those patents in relation to Actos®").

[119] *Id.* at 1-2.

[120] *Id.* at 6-7 (emphasis in original). Teva further stated:

> January 2011 is the month that the '777 patent expires and when the FDA would be free to approve Teva's Actos® ANDA (which already has tentative approval) but for the issue raised by this counterclaim. If, however, Teva is required to file paragraph IV certifications to drug product claims in the '584 and '404 patents, then Teva will be blocked from launching until 181 days after the first-filers trigger their exclusivity. Certain first-filers have announced settlements with Takeda in which they likely will not launch their generic versions of Actos® until August 2012. If Teva is required to wait 181 days after those launch dates to obtain FDA approval, that would delay Teva's approval until February 2013.

Id. at 7 n.5.

9. Takeda negotiates the December 2010 pact with Teva.

In the second half of 2010, sensing the risk that Teva would prevail on its counterclaim and enter the market with generic ACTOS as early as January 2011 with section viii statements, Takeda folded Teva into the conspiracy.[121]

On December 22, 2010, Takeda and Teva entered into an agreement. Although Teva had previously complained of Takeda's efforts to delay generic ACTOS launch for over a year-and-a-half, Teva now flip-flopped and *agreed* to that delay. It would (i) drop its challenges to Takeda's patents with respect to both ACTOS and ACTO*plus* met, (ii) drop its counterclaim asserting that Takeda had submitted false and misleading patent information as to the combo patents, and (iii) stay out of the market with generic ACTOS until August 17, 2012, and stay out of the market with generic ACTO*plus* met until the date on which Mylan entered the market.[122]

In exchange, Takeda allowed Teva to enjoy the fruits of the falsely created 180-day exclusivity (as had been planned in the March 2010 pact):

First, Takeda gave Teva an authorized generic distributorship for ACTOS in which Teva could enter the market at the same time as the first wave generics, *i.e.*, August 17, 2012. Takeda's ability to do so had been expressly reserved in the March 2010 pact as a means by which to entice Teva to drop its section viii efforts and join the delay of generic ACTOS.[123]

Second, Takeda agreed that – with the exception of the "licenses" to which it had already agreed with Mylan, Ranbaxy, and Actavis – Takeda would not grant any other generic drug manufacturer a release of patent liability for entering the ACTOS market earlier than 180

[121] Compl. ¶¶ 286-89.

[122] Compl. ¶¶ 290, 295.

[123] Compl. ¶ 299; *see* Ex. 1 to Kokkines Decl. (Ranbaxy Agreement), Section 3.1(c); Ex. 2 to Kokkines Decl. (Mylan ACTOS Agreement), Section 3.1(c); Ex. 4 to Kokkines Decl. (Watson Agreement), Section 3.1(c).

days after Teva entered the market.[124] This assured Teva that it would be the last to partake in the falsely created 180-day exclusivity. Takeda also agreed it would not enter with its own authorized generic during that period.[125]

Finally, Takeda gave Teva an exclusive authorized generic distributorship for ACTO*plus* met through which Teva could enter the market at the same time as Mylan, *i.e.*, December 2012 (or August, under certain circumstances that did come to pass).[126] Of course, Takeda and Teva agreed to the same coordinated launch provisions as the first wave generics, assuring the coordinated timing of entry for all.[127]

The combination of disincentives created by the March 2010 pact, coupled with the promises made by Takeda in the December 2010 pact, caused Teva to drop its section viii statement approach to launching generic ACTOS by the end of January of 2011 and to stay out of the ACTOS and ACTO*plus* met markets longer than it otherwise would have. The falsely created 180-day exclusivity for ACTOS generics would be perpetuated well beyond January 2011, with Teva now joining the first wave generics in the benefits of that exclusivity.

III. LEGAL STANDARD

On a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a court must look to the plaintiffs' operative complaint for the controlling facts, accept all factual allegations as true, and "construe all reasonable inferences that can be drawn from the complaint in the light most favorable to the plaintiff."[128] To survive a motion to dismiss, a plaintiff need only allege "enough facts to state a claim to relief that is plausible on its face."[129] The plausibility

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[124] Compl. ¶ 302.

[125] *See* Ex. 5 to Kokkines Decl. (Teva Agreement), Section 3.2.

[126] Compl. ¶¶ 304, 306.

[127] Compl. ¶¶ 303, 307.

[128] *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012).

[129] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

standard is not akin to a "probability requirement," but "simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of [the claim]."[130] "Because plausibility is a standard lower than probability, a given set of actions may well be subject to diverging interpretations, each of which is plausible."[131] The court cannot rely on any materials outside the operative complaint to "make a finding of fact that *controvert*[s] the plaintiff's own factual assertions."[132]

IV. ARGUMENT

Section 2 of the Sherman Act forbids monopolization "or attempt[s] to monopolize, or combine or conspire with any other person or persons, to monopolize."[133] Section 1 of the Sherman Act provides "[e]very contract, combination . . . or conspiracy, in restraint of trade or commerce . . . is declared to be illegal."[134] The Clayton Act authorizes private parties to seek treble damages for past injury caused by conduct that violates the antitrust laws, including §§ 1 and 2 of the Sherman Act.[135]

The direct purchasers allege claims under both §§ 1 and 2 of the Sherman Act. They have standing to sue for overcharge damages in antitrust cases[136] and are entitled to recover the entire amount of a proven overcharge.[137]

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[130] *Id.* at 556.

[131] *Anderson News*, 680 F.3d at 184.

[132] *Global Network Commc'ns, Inc. v. City of New York*, 458 F.3d 150, 156 (2d Cir. 2006).

[133] 15 U.S.C. § 2.

[134] 15 U.S.C. § 1.

[135] 15 U.S.C. § 15(a) ("Except as provided in subsection (b), any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee.").

[136] *Ill. Brick Co. v. Illinois*, 431 U.S. 720 (1968).

[137] *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 392 U.S. 481 (1968).

A. The complaint alleges Takeda violated § 2 of the Sherman Act by submitting false patent information to the FDA.

1. Submitting false patent information to the FDA violates § 2 of the Sherman Act.

"The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[138] Takeda does not challenge the monopoly power allegations.

Falsehoods to public officials can be exclusionary conduct that violates the Sherman Act.[139] "The supplying of fraudulent information . . . threatens the fair and impartial functioning of . . . agencies and does not deserve immunity from the antitrust laws."[140] Courts recognize agencies "rely on the information presented by the parties before them" because they "seldom, if ever, have the time or resources to conduct independent investigations."[141] The

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[138] *United States v. Grinnell Corp.*, 384 U.S. 563, 571-72 (1966).

[139] *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972) ("Misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process."); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965) ("Proof of this assertion [that the patentee obtained the patent by knowingly and willfully misrepresenting facts to the Patent Office] would be sufficient to strip [the patentee] of its exemption from the antitrust laws."); *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1063 (9th Cir. 1998) (A plaintiff "can overcome a 12(b)(6) motion if his allegations demonstrate that [the defendant] so misrepresented the truth to the Department [of Health] that the entire [administrative] proceeding was deprived of its legitimacy."); *Whelan v. Abell*, 48 F.3d 1247, 1255 (D.C. Cir. 1995); ("However broad the First Amendment right to petition may be, it cannot be stretched to cover petitions based on known falsehoods."); *St. Joseph's Hosp., Inc. v. Hosp. Corp. of Am.*, 795 F.2d 948, 955 (11th Cir. 1986) (holding misrepresentations to a governmental agency are not immune from antitrust liability); *Confederated Tribes of Siletz Indians of Or. v. Weyerhaeuser Co.*, 00-cv-1693, 2003 WL 24901381, at *7 (D. Ore. July 5, 2003) (upholding jury verdict finding antitrust liability for "knowingly [making] false statements to the Oregon Department of Forestry to obtain an exemption from log export regulations" that "had the effect of denying . . . logs to the Plaintiff mills"); Phillip E. Areeda & Herbert J. Hovenkamp, *Antitrust Law* ¶203f (3d ed. 2006) ("Several courts have regarded as actionable under the antitrust laws the competitive injury that flows from the knowing submission of false information to a government body."); *cf. Armstrong Surgical Ctr., Inc. v. Armstrong Cnty. Mem'l Hosp.*, 185 F.3d 154, 164 n.8 (3d Cir. 1999) (distinguishing case other fraudulent misrepresentation cases, including *Walker Process*, where agencies were "wholly dependent upon the antitrust defendants for the factual information" on which the agency "predicated" its action).

[140] *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240, 1261 (9th Cir. 1982); *see also Israel v. Baxter Labs., Inc.*, 466 F.2d 272, 278 (D.C. Cir. 1972) (stating that misrepresentation of safety and efficacy data to the FDA should not be allowed "to hide behind the cloak of an antitrust exemption").

FDA has limited resources, making it dependent on truthful information from pharmaceutical companies.[142]

The Second Circuit and other courts recognize that the prohibition on falsehoods extends to misrepresentations affecting the agency's execution of its non-discretionary or ministerial duties.[143]

In *Litton Systems, Inc. v. American Telephone & Telegraph Co.*,[144] the Second Circuit rejected AT&T's pleas for antitrust immunity where AT&T made material misrepresentations in a tariff filing it was required by law to file with the FCC.[145] The FCC played a purely ministerial role in accepting the tariff filing – it did not pass upon the legality or propriety of a submitted tariff.[146] The *Litton* court observed that no antitrust immunity attached to the tariff filing because the tariff-setting was "private commercial activity" and the "decision to impose and maintain the [] tariff was made in the AT&T boardroom, not at the FCC."[147] "AT&T [could not] cloak its actions in *Noerr-Pennington* immunity simply because it is required, as a regulated monopoly, to disclose publicly its rates and operating procedures."[148]

Litton's logic applies in the prescription pharmaceutical context. The FDA plays a non-

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[141] *Clipper Exxpress*, 690 F.2d at 1262.

[142] Compl. ¶¶ 77, 86-87; *see also aaiPharma Inc. v. Thompson*, 296 F.3d 227, 237 (4th Cir. 2002) (The FDA lacks "both the resources and expertise to police the correctness of Orange Book listings.").

[143] *See, e.g.*, *Litton Sys., Inc. v. Am. Tel. & Tel. Co.*, 700 F.2d 785, 807 (2d Cir. 1983); *Woods Exploration & Producing Co. v. Aluminum Co. of Am.*, 438 F.2d 1286, 1298 (5th Cir 1971) (oil company could face antitrust liability for material misrepresentations to the Texas Railroad Commission affecting competitors' oil rations, because Texas law set a predictable formula as to how much oil could be drawn from an oil field); *DeLoach v. Philip Morris Cos., Inc.*, No. 00-cv-1235, 2001 WL 1301221, at *2, *12 (M.D.N.C. July, 24, 2001) (antitrust liability could be established against tobacco companies who falsely reported the amount of tobacco they intended to purchase, which, when inputted into the U.S. Department of Agriculture's non-discretionary "statutory formula," artificially depressed the price of tobacco, harming tobacco farmers).

[144] 700 F.2d 785 (2d Cir. 1983).

[145] *Id.* at 807-08.

[146] *Id.*

[147] *Id.* at 807.

[148] *Id.*

discretionary, "purely ministerial role" in listing a patent in the Orange Book.[149] As in *Litton*, the decision of what patent claims are included in a brand's patent information and how those claims are described (*i.e.*, as product or method-of-use claims) is made in the brand's boardroom, not at the FDA. And a brand company cannot escape antitrust liability simply because the Hatch-Waxman amendments require it, as a regulated entity, to submit patent information describing the types of patent claims covering its RLD.

Courts have found that brand companies' misrepresentations to the FDA about their patent coverage leads to inaccurate information being listed in the Orange Book, delays generic launch, and violates § 2 of the Sherman Act.[150] In *In re Buspirone Patent Litigation*,[151] the plaintiffs – including now-defendants Mylan and Actavis – alleged that a brand company fraudulently submitted patent information claiming that a patent covered uses of buspirone and then exploited the listing to gain a competitive advantage (*i.e.*, bringing patent infringement suits against generics, thereby triggering automatic 30-months stays).[152] Bristol-Myers argued

[149] *aaiPharma*, 296 F.3d at 230.

[150] *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 372-73 (S.D.N.Y. 2002) (denying motion to dismiss antitrust claims where the complaint alleged a brand company's patent information submissions falsely claimed the patent covered approved uses of buspirone); *Abbott Labs. v. Alra Lab., Inc.*, No. 92-cv-5806, 1993 WL 293995, at *2-3 (N.D. Ill. Aug. 4, 1993) (declining to dismiss claim of fraud based on allegation that brand company "knowingly and falsely represented to the FDA" that a patent covered Depakote); *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 532 (D.N.J. 2004) (denying motion to dismiss because, "[w]ithin the maze of Hatch-Waxman, if a patent-holder's actions . . . use a lawful patent to manipulate the ANDA process, such actions could lead to anticompetitive effects in the relevant market"); Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.32b (Supp. 2012) (Where a patentee "list[s in the Orange Book] either a clearly invalid patent or one that obviously does not cover the drug claimed," allowing the patentee to acquire or maintain market power, "the abuse of the FDA process should be actionable under § 2 [of the Sherman Act]."); Susan A. Creighton et al., *Cheap Exclusion*, 72 Antitrust L.J. 975, 984 (2005) ("If the patent listings do not meet the statutory and regulatory requirements for inclusion in the Orange Book, the listing may constitute an unlawful restraint on competition."). *Cf. Stop & Shop Supermarket Co. v. SmithKline Beecham Corp.*, No. 03-cv-4578, 2005 WL 1213926, at *4 (E.D. Pa. May 19, 2005) (recounting allegations that brand company "knowingly and willfully ma[de] false and misleading representations to the FDA to obtain multiple listings in the Orange Book").

[151] 185 F. Supp. 2d 363.

[152] *Id.* at 366.

that its conduct was not actionable under the Sherman Act.[153] Judge Koeltl denied Bristol-Myers's motion to dismiss, holding that its submission of false patent information fell within the Sherman Act's reach:

> Where, as here, it is alleged that a party with intimate legal knowledge about a patent has made knowingly false statements about its scope to a governmental agency that has neither the authority nor the ability to determine the accuracy of the representations and is instead making publication decisions that can have palpable anticompetitive effects, the *Walker Process* exception applies [and plaintiffs' Sherman Act §2 claim stands].[154]

Judge Koeltl observed that,

> [T]he FDA is required by law to publish the information [provided by Bristol-Myers] in the Orange Book. Hence, the FDA's actions are non-discretionary and do not reflect any decision as to the validity of the representations in an Orange Book listing.[155]

And he concluded that,

> [C]onduct through which private parties seek to achieve anticompetitive aims by making representations to the government in circumstances where the government does not perform any independent review of the validity of the statements, does not make or issue any intervening judgment and instead acts in direct reliance on the private party's representations [is not immune to antitrust scrutiny].[156]

A year later, Bristol-Myers paid $535 million to resolve the buspirone litigation, including the antitrust claims brought by Mylan and Watson/Actavis.[157]

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[153] *Id.* at 373. The *Buspirone* defendant claimed the *Noerr-Pennington* doctrine immunized its fraudulent petitioning because its FDA submission was not objectively baseless. *Id.* at 369. The district court held that *Noerr-Pennington* did not apply and that plaintiffs had, in any event, alleged exceptions to *Noerr-Pennington*. Here, the complaint alleges such exceptions, Compl. ¶¶ 169, 171, and the defendants have not argued for *Noerr-Pennington* immunity.

[154] *Burpirone*, 185 F. Supp. 2d at 374 (internal citation omitted).

[155] *Id.* at 371 (internal citations omitted).

[156] *Id.* at 370.

[157] *See In re Buspirone Patent Litig. Multidistrict Patent Litig.*, 60 Fed. App'x 806 (Fed. Cir. 2003); Melody Peterson, *Bristol-Myers Squibb to Pay $670 Million to Settle Numerous Lawsuits*, N.Y. Times, Jan. 8, 2003, *available at*

2. The complaint alleges Takeda submitted false patent information to the FDA.

The direct purchasers allege that Takeda falsely represented to the FDA that the '584 and '404 patents' *product claims* covered ACTOS.[158] They did not.[159] And those misrepresentations – reiterated over the years – set in motion a chain of events that wrongfully delayed generic entry.[160] As defendant Teva has recognized, "Takeda's wrongful conduct likely will mean that there will be *no* generic version of Actos® available to consumers for more than 18 months after such products otherwise would be available."[161]

a. The product claims in the '584 and '404 patents do not cover the product ACTOS.

The '584 and '404 patents each include both claims covering a combination product, and a method-of-using the ACTOS active ingredient in that combination.[162] As a matter of law, the combination product claims do not cover ACTOS alone. The Supreme Court long ago held that "[i]f anything is settled in the patent law, it is that the combination patent covers only the totality of the elements in the claim and that no element, separately viewed, is within the

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http://www.nytimes.com/2003/01/08/business/bristol-myers-squibb-to-pay-670-million-to-settle-numerous-lawsuits.html.

[158] Compl. ¶¶ 170, 176. The direct purchasers do not dispute that the '584 and '404 patents were required to be listed in the Orange Book. And we accept, of course, that those patents had *method-of-use* claims that were properly identified as covering ACTOS (though the method-of-use claims could be carved out with a section viii statement, and would not delay generic entry).

[159] Compl. ¶¶ 167, 173.

[160] Compl. ¶¶ 186, 229-30.

[161] Compl. ¶ 237.

[162] Compl. ¶¶ 166, 172; Ex. 6 to Decl. of Adam R. Lawton, ECF No. 66-1; Ex. 7 to Decl. of Adam R. Lawton, ECF No. 66-2.

grant."[163] "Infringement of a combination occurs only through a combination comprising every one of its elements[.]"[164]

Takeda's own actions confirm that the product claims in the '584 and '404 patents do not cover ACTOS. In its many lawsuits against the generics over ACTOS, Takeda *never* accused a generic of directly infringing the *product claims* in the '584 and '404 patents. Takeda's many infringement lawsuits only accused the generics of infringing *by inducement* the *method-of-use* claims of those patents.[165] If Takeda believed the product claims in its patents did claim ACTOS, why did it never sue the generics for directly infringing those claims?

b. Takeda repeated its submissions of false information to the FDA.

Takeda submitted false patent information regarding the '584 patent in 1999,[166] and regarding the '404 patent in 2002.[167] Takeda doubled down on these false statements in 2009 and 2010, in response to the citizen petition.[168] And it insisted that "section viii statements alone [were] insufficient," requesting that the FDA "direct any companies that have submitted [ANDAs] referencing Actos to submit complete patent certifications to these patents."[169]

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[163] *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 344 (1961) (internal citations omitted).

[164] *Guide v. Desperak*, 249 F.2d 145, 147 (2d Cir. 1957) (internal citation omitted); *see also Rowell v. Lindsay*, 113 U.S. 97, 102 (1885) ("The patent being for a combination, there can be no infringement unless the combination is infringed.").

[165] *See* Am. *Mylan* Compl. ¶¶ 50, 53, 60, 63, 69, 77 (alleging that Mylan launched generic pioglitazone with the intention that physicians prescribe it in combination therapy – a method of using Actos – and that therefore Mylan intended to induce infringement of the '584 patent); *Watson* Compl. ¶¶ 44, 46, 54, 56, 62, 69 (same, as to Watson); Compl. ¶¶ 42, 44, 54, 58, 59, 64, *Takeda Chem. Indus. Ltd. v. Ranbaxy Labs., Ltd.*, No. 03-cv-5055 (D.N.J. Oct. 23, 2003) ("*Ranbaxy* Compl.") (same, as to Ranbaxy); Compl. ¶¶ 101, 103-04, 109, 111-12, *Takeda Pharm Co. Ltd., v. Teva Pharm. Indus., Ltd.*, No. 09-cv-4665 (S.D.N.Y. May 18, 2009) ("*Teva* Compl.") (same, as to Teva).

[166] Compl. ¶ 170.

[167] Compl. ¶ 176.

[168] Compl. ¶¶ 232, 237.

[169] Ex. 9 to Lawton Decl. at 3.

c. The law does not condone Takeda's false patent information as "reasonable."

Takeda tries to justify its conduct by claiming that it could "reasonably" assert that the '584 and '404 patents would be infringed if a person not licensed by Takeda manufactured, sold, or used generic ACTOS, and that this made the characterization of those patents as claiming the ACTOS product itself proper.[170] This is wrong as a matter of law.

The language of the statute. The FDCA and FDA regulations require NDA applicants to identify, by type, patents that both (1) claim the drug described in the NDA or claim a method of using the drug described in the NDA, *and* (2) that could reasonably be asserted if someone else made or sold the drug before those patents expire:

> The applicant shall file with the application the patent number and the expiration date of *any patent which claims the drug* for which the applicant submitted the application *or which claims a method of using such drug* and with respect to which a claim of patent infringement could *reasonably be asserted* if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.[171]

Both the statute and implementing regulations distinguish between drug product claims and method-of-use claims.[172] The regulations require that NDA applicants only identify product claims that cover the drug described in the NDA: "For patents that claim a drug substance or drug product, the applicant shall submit information *only* on those patents that *claim a drug product that is the subject of a pending or approved application*, or that claim a drug substance that is a component of such a product."[173] The FDA's comments to the regulations instructed applicants "to identify, to the best of their ability, the type of patent covering the

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[170] Takeda Br. 9-10.

[171] 21 U.S.C. § 355(b)(1) (emphasis added).

[172] *Id.*; ANDA Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. at 50,363.

[173] ANDA Regulations: Patent and Exclusivity Provisions, 59 Fed. Reg. at 50,344 (Oct. 3, 1994) (emphasis added).

drug or drug product. This information will help FDA determine which claims cover the drug or drug product and which claims cover a method of use."[174]

The comments also cautioned that misreporting patent information could "misle[a]d" potential applicants or "result in injury to other applicants."[175]

The purposes of the statute. Congress and the FDA require brand companies to provide this patent information "[t]o facilitate the approval of generic drugs as soon as patents allow[.]"[176] The entire regulatory framework is geared around the expectation that a brand company will accurately describe only the claims that actually cover the RLD and accurately identify the type of claim.[177]

The distinction between product claims and method-of-use claims is vital. As the Supreme Court recognizes, "whether section viii is available to a generic manufacturer depends on how the brand describes its patent."[178] Congress decided that method-of-use claims should not tie up otherwise approvable ANDAs.[179] So when a brand company tells the FDA that it has only method-of-use claims, a generic can carve out the patented uses and submit a section viii

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[174] *Id.* (noting, in response to comments, "*if* the formulation patent claimed *the drug product in the application*, the applicant must file information on that patent" (emphasis added)).

[175] *Id.*

[176] *Caraco*, 132 S. Ct. at 1676.

[177] *Id.* at 1684 ("An overbroad use code therefore throws a wrench into the FDA's ability to approve generic drugs as the statue contemplates.").

[178] *Id.* at 1677; *see id. at* 1687 ("Whether a brand lists [in the Orange Book] a patent that covers no use or describes a patent on one use as extending to others, the brand submits misleading patent information to the FDA. . . . And the brand's action may in either case delay or block approval of a generic drug that infringes no patent – and that under [Hatch-Waxman] should go to market."); *see also In re Biovail Corp.*, F.T.C. No. C-4060 (Oct. 4 , 2002) (consent order prohibiting brand manufacturer from "the listing or continued listing of any patent in the Orange Book in violation of applicable law" in case where brand manufacturer "was aware" at the time it listed its additional patent in the Orange Book that said additional patent did not "cover the formulation . . . it was marketing").

[179] 21 U.S.C. § 355(j)(2)(A)(viii); *Caraco*, 132 S. Ct. at 1681-82 ("[A]s Congress understood," "a single drug may have multiple method of use, only one of which a patent covers," so "[t]he statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones.")

statement, the FDA may then approve the generic, and the generic may launch.[180] But when a brand company tells the FDA that it has product claims covering its drug, the FDA will require a paragraph IV certification, grant an exclusivity to the first filer, impose a 30-month stay (once the brand sues for infringement), and not approve the ANDA until the expiration of the stay or a final decision on the infringement merits in the generics' favor.[181]

Takeda's patent information submissions were not "proper." Takeda asserts "there was nothing improper in Takeda's patent submissions."[182] To make the argument, Takeda disingenuously quotes only half of the applicable statute, relying on the "reasonably asserted" prong but omitting the key "*patent that claims the NDA drug*" prong, probably because the product claims in the patents do not claim ACTOS.[183] Takeda's brief fails to address the FDA's regulations, comments to the regulations, and the purpose of the statute (as recognized by the Supreme Court in *Caraco*).

And as a matter of law, "the propriety or lawfulness of the predicate activities of a monopolization scheme do not determine whether the scheme itself is actionable or unlawful."[184] Takeda's "reasonable" argument fails.

One might expect Takeda to make a cute argument that its submissions did not amount to an outright falsehood, as it only said the patents had product claims, not that they claimed the ACTOS product. But the submissions were made in the NDA file for ACTOS;[185] why else

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[180] Compl. ¶ 154.

[181] Compl. ¶ 153. There is, technically, a third option: a generic company could choose to wait out the expiration of any valid patents before launching, by filing a "paragraph III" certification. 21 U.S.C. § 355(j)(2)(A)(vii)(III). None of the generics here did so.

[182] Takeda Br. 9.

[183] Takeda Br. 9 ("The Hatch-Waxman Act mandated that Takeda list any patent with respect to which a claim of patent infringement *could reasonably be asserted* if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.").

[184] *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 360 & n.23 (D.N.J. 2009).

[185] Ex. 9 to Lawton Decl. at 7. (regarding the '584 patent, writing: "Type of Patent: Drug Product, Method of Use.")

say the patents had product claims if the claims were not being characterized as claiming the ACTOS product? And, in any event, Takeda's later reiterations to the FDA were explicit, "confirming" the earlier misrepresentations and insisting the FDA require patent certifications because of ACTOS product claims "because these two patents contain both composition claims and method-of-use claims."[186]

And consider the context: Takeda made these submissions against the backdrop of the statute, regulations, and purposes of the Act of ensuring that use patents do not prolong access to generics for unpatented utilization.

Takeda argues Judge Cote's 2007 decision declining to dismiss Takeda's induced infringement claims in the Sandoz case supports its "reasonableness" argument.[187] But Judge Cote's Rule 12(b)(6) rulings only addressed whether Takeda had adequately alleged inducement of method-of-use claims.[188] Her rulings do not hold the '584 or '404 patents claim the ACTOS product itself. In fact, Judge Cote wrote that the '584 and '404 patents "cover the combination of pioglitazone with other antidiabetic agents";[189] perforce that excludes them claiming ACTOS alone.

And Judge Cote observed that "Sandoz's arguments require the weighing of evidence and inferences," noted that "Takeda will not be entitled to a *de facto* extension of the life of the '777 patent through frivolous [patent infringement] claims premised on the theory that its combination-use patents are being infringed." and concluded that "[j]udgment on the merits . . . must await the completion of discovery, summary judgment, and/or trial."[190]

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[186] *Id.*

[187] Takeda Br. 9.

[188] *Takeda Pharms. Co. Ltd. v. Sandoz, Inc.*, No. 07-cv-3844, 2007 WL 2936208, at *2 (S.D.N.Y. Oct. 9, 2007) (addressing a motion to dismiss infringement claims, unrelated to Orange Book listings).

[189] *Id.* at *1

[190] *Id.* at *4–5.

B. The complaint alleges the defendants violated § 1 of the Sherman Act by conspiring to limit generic competition for ACTOS and ACTOplus met.

1. The complaint alleges a violation of § 1 of the Sherman Act.

Rather than address the conspiracy-related allegations in *this* complaint,[191] the defendants made the strategic choice to mischaracterize the direct purchaser class plaintiffs' allegations as "materially indistinguishable from those alleged and rejected in the *End Payor* case."[192] But the direct purchaser class plaintiffs' allegations should be addressed on their merits. And they make clear that:

1. Takeda's false information regarding the '584 and '404 patents created an opportunity for would-be generic manufacturers to take advantage of falsely created, but highly valuable, 180-day exclusivity period;

2. The first wave generics – Mylan, Ranbaxy, and Actavis – knew Takeda's patent information for the '584 and '404 patents was false, that it unlawfully created a valuable 180-day exclusivity, that each was taking advantage of, and cashing out on, falsely created exclusivity;

3. Takeda and the first wave generics knew their March 2010 agreements would prolong for many months a bottleneck impairing the ability of later ANDA filers (Sandoz, Torrent, Aurobindo) and subsequent filers to gain market entry – they knew their agreements were intended to accomplish a common, unlawful end;

4. The first wave filers knew of each other's pending ANDAs, were party to the same patent litigation, and settled within days of each other on materially identical terms. All agreed: (i) to the same August 17, 2012 delayed entry date and substantially similar coordination clause terms and otherwise agreed; (ii) to maintain the paragraph IV certifications as to the '584 and '404 patents but not to ever contest the validity, enforceability, or infringement of those patents; (iii) not to assist third-parties challenging the '584 and '404 patents; (iv) to withdraw all, and thereafter never make, any section viii method-of-use carve-out statements, and; (v) to keep the settlement terms strictly confidential,

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[191] *See, e.g.*, Compl. ¶ ¶ 248-79.

[192] Joint Br. 25. Because the defendants made the deliberate choice to ignore the direct purchasers' new and substantially revised conspiracy-related allegations, this Court should not entertain any argument in reply challenging their sufficiency. *See Knipe v. Skinner*, 999 F.2d 708, 711 (2d Cir. 1993) (stating that "[a]rguments may not be made for the first time in a reply brief"); *Nat'l Labor Relations Bd. v. Star Color Plate Serv.*, 843 F.2d 1507, 1510 n.3 (2d Cir. 1988) (rejecting party's "attempts to raise for the first time [a new question] in its reply brief"); *Rowley v. City of New York*, No. 00 Civ. 1793, 2005 WL 2429514, at *5-6 (S.D.N.Y. Sept. 30, 2005) (refusing to entertain arguments in reply that could have been raised in opening brief); *cf. Bendix Autolite Corp. v. Midwesco Enters. Inc.*, 486 U.S. 888, 893-97 (1988) (refusing to evaluate an argument the Sixth Circuit did not consider because it was first raised in a reply brief).

5. Each agreement permitted hub-player Takeda to disclose to all would-be generic competitors the otherwise secret provisions embodying the delayed launch date, the maintained and substituted paragraph IV certifications, and coordination clauses;[193]

6. The first wave generics knew that the same delayed entry date, paragraph IV, and coordination clauses in each settlement – the *only* settlement terms that could be communicated *directly* to all other would-be generic competitors – assured that no generic manufacturer (whether participating in the conspiracy or not) would enter the market ahead of any participating conspirator;

7. The terms authorizing Takeda to share the settlement terms with other would-be generic competitors existed only because the parties *intended* that agreement to be shared with other would-be competitors as either an invitation to join the conspiracy or a deterrent that market entry outside the conspiracy would invite ruinous competition from all conspirators;

8. The economic effect of the coordination clause forced Teva, whose section viii method-of-use carve-out approach otherwise was in competition to beat out the first filers' market entry, to join the conspiracy and participate in the fruits of the 180-day exclusivity that was wrongfully created by Takeda's false patent information and expressly affirmed in each of the first filers' settlement agreements;

9. Under the December 2010 pact Teva joined the conspiracy in a remarkable flip-flop. Back in March 2010 it took the position that Takeda's false patent information would wrongfully delay generic ACTOS entry for over a year and a half, and bottleneck its entry. But under the December 2010, Teva was brought into the conspiracy and allowed to share in the fruits of the (previously considered unlawful by Teva) 180-day exclusivity; now that it got paid off, Teva was willing to join the coordinated effort to delay generic entry; and

10. The defendants employed the same tactics to incorporate ACTO*plus* met into the mix.

[193] The defendants filed the at-issue settlement agreements under seal in February 2016. At the time the plaintiffs filed the Second Consolidated Amended Complaint in November 2015, the extent to which each settlement agreement contained the same material terms, as set forth in the text above, was not then known.

2. Violations of § 1 of the Sherman Act may be shown by direct and circumstantial evidence.

A tacit agreement may be inferred from the conspirators' actions and conduct, rather than through express communications.[194] Circumstantial evidence that meets this standard may demonstrate, for example, parallel behavior that would probably not result from chance, "'coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties.'"[195] "Plus factors" that may raise an inference of conspiracy include "'a common motive to conspire, evidence that shows that the parallel acts were against the apparent individual economic self-interest of the alleged conspirators, and evidence of a high level of interfirm communications.'"[196]

Courts "do treat separate bilateral agreements as evidence of a single conspiracy when the agreements are sufficiently interdependent and made in the context of other plus factors suggesting coordination."[197] Interdependence requires determining "whether the activities of one aspect of the scheme are necessary or advantageous to the success of another aspect of the

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[194] *Brown v. Pro Football*, 518 U.S. 231, 241 (1996) ("Antitrust law also sometimes permits judges or juries to premise antitrust liability upon little more than uniform behavior among competitors, preceded by conversations implying that later uniformity might prove desirable . . . or accompanied by other conduct that in context suggests that each competitor failed to make an independent decision." (internal citations omitted)). Courts recognize that when competitors "devise some subtle, unique form of conspiracy tailored to best serve their own purposes which purposely leaves few tracks or fingerprints, it may violate the law even though it cannot be easily accommodated in the familiar mold of a simple and limited conspiracy." *United States v. Consol. Packaging Corp.*, 575 F.2d 117, 126 (7th Cir. 1978).

[195] *Twombly*, 550 U.S. at 556 n.4 (quoting 6 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1433 (2d ed. 2003)).

[196] *United States v. Apple, Inc.*, 791 F.3d 290, 315 (2d Cir. 2015) (quoting *Mayor & City Council of Baltimore, Md. v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013)); *In re Nexium Esomeprazole Antitrust Litig.*, 42 F. Supp. 3d 231, 250-51 (D. Mass. 2014) (*"Nexium II"*).

[197] *Nexium II*, 42 F. Supp. 3d at 252 (citing *Interstate Circuit, Inc. v. United States*, 306 U.S. 208, 226 (1939)); *see also Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990) (per curium); *Apple*, 791 F.3d at 316, 320 (considered in context, independently lawful contracts can by themselves "provide strong evidence [of a] consciously orchestrated[ ] conspiracy").

scheme."[198] And "[t]he "'overlap'" requirement can be satisfied by the pervasive involvement of a single "'core conspirator.'"[199]

Here, the defendants shared a common goal of maintaining the falsely created 180-day exclusivity for ACTOS generics. The benefits of the individual agreements would only accrue if all generic defendants agreed to: (i) delay generic entry until the same date; (ii) to maintain the false 180-day exclusivity created by the paragraph IV certifications on the '584 and '404 patents while simultaneously agreeing to (a) not ever contest the validity, enforceability, and/or infringement of those patents, and (b) withdraw all, and to never make any further, section viii method-of-use carve-out statements.[200]

The agreements contain explicit interdependent terms that link each settling generic defendant's entry date to the entry of its competitors and provides each with the assurance that its agreement to stay off the market would be contingent upon all others doing the same.[201] The uniform delayed entry date, coordination clause, required paragraph-IV certifications, and provision allowing those terms to be shared with other would-be competitors ensured that no other generic – no matter how much time and resources it spent in its litigation against Takeda, and no matter how successful the generic drug manufacturer was in the litigation – could enter the market before Mylan, Ranbaxy, and Actavis.[202]

The agreements created "a set of economic incentives" that made "attractive" each generic defendant's agreement to postpone entering the market – an agreement that squarely contravened each generic defendant's economic self-interest to be the first generic to enter the

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[198] *United States v. Portela*, 167 F.3d 687, 695 (1st Cir. 1999) (internal quotations omitted).

[199] *Id.* at 695 (quoting *United States v. Wilson*, 116 F.3d 1066, 1076 (5th Cir. 1997)).

[200] Compl. ¶¶ 248- 59.

[201] Compl. ¶¶ 257-59, 262.

[202] Compl. ¶ 258-59, 292.

market – only if all the other would-be generic competitors agreed to the same terms.[203] The same delayed entry date, coordination clause, section-viii-to-paragraph-IV swap,[204] and provision allowing those terms to be shared with other would-be competitors in each settlement provided the interdependence necessary to ensure the success of the scheme.

Takeda was the hub of this conspiracy. By ensuring each generic defendant that all of their agreements had substantively identical terms effectuating delayed generic entry, Takeda provided the means for maintaining Takeda's monopoly profits for the benefit of all conspirators.[205] The agreements all authorized Takeda to share the terms of the otherwise secret agreements *with other generic competitors*, further evincing the agreements' interdependence and the overall conspiracy.[206] That would only be so if sharing terms with other competitors, in the hopes that they would join the scheme, was part of the plan from the start.

It matters not that Takeda offered different inducements to each generic. Takeda insisted on, and all generics agreed to, materially identical provisions accomplishing delayed generic entry until August 17, 2012 and manipulating the patent certifications/statements to shore up the wrongful exclusivities.[207] The only reason a rational brand company would agree to this set of terms that might (hypothetically) permit acceleration of competition is if the clause *reduces the likelihood of the competition* in the first place.

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[203] *See Apple*, 791 F.3d at 316-17 (affirming conspiracy on the basis of separate bilateral contracts, all executed near in time to each other and containing materially similar terms, because each was "attractive only if [defendants] acted collectively").

[204] *See Sebelius*, 2012 WL 6968224, at *6 n.7, *19 n.22.

[205] *Nexium II*, 42 F. Supp. 3d at 254 (holding that "the similarities between the agreements with the generic defendants "demonstrate[d] a degree of interdependence suggesting a single agreement, even if no such agreement was expressly made").

[206] Compl. ¶ 252.

[207] Joint Br. 26-27.

That the December 2010 pact (with Teva) occurred nine months after the March 2010 pact is irrelevant. In *United States v. Masonite Corp.*,[208] the United States alleged that a series of agreements between Masonite and other hardboard manufacturers that followed the settlement of patent litigation constituted an unlawful horizontal combination in violation of § 1 of the Sherman Act. The Supreme Court reversed the district court's dismissal after a full trial found insufficient evidence of concerted action:

> It is not clear at what precise point of time each appellee became aware of the fact that its contract was not an isolated transaction but part of a larger arrangement. But it is clear that, as the arrangement continued, each became familiar with its purpose and scope. . . . The circumstances surrounding the making of the 1936 agreements and the joinder in 1937 of the two other companies leave no room for doubt that all had an awareness of the general scope and purpose of the undertaking. As this Court stated in the *Interstate Circuit* case: ". . . Acceptance by competitors, without previous agreement of an invitation to participate in a plan, the necessary consequence of which, if carried out, is restraint of interstate commerce, is sufficient to establish an unlawful conspiracy under the Sherman Act."[209]

Here, the generic defendants knew that concerted action was contemplated and invited, and by entering into the settlement agreements, each ratified their respective participation in the conspiracy.[210]

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[208] 316 U.S. 265 (1942).

[209] *Id.* at 275 (quoting *Interstate Circuit Inc. v. United States*, 306 U.S. 208, 226-27 (1939)) (internal citations omitted).

[210] *Apple*, 791 F.3d at 317 ("By the very act of signing [the] Contract with Apple . . . each of the Publisher Defendants signaled a clear commitment to [the scheme], thereby facilitating their collective action."). The fact that the generic defendants joined the conspiracy at different times is immaterial. *See United States v. Cont'l Group, Inc.*, 603 F.2d 444, 452, 453 (3d Cir. 1979) (holding, in a case where conspirators joined ten and nineteen years after inception, no need "to prove that [each defendant] participated in the conspiracy from its inception, but only that he knowingly became a member of the ongoing conspiracy" (internal citation omitted)); *see also United States v. Nat'l Lead Co.*, 332 U.S. 319, 325-27 (1947) (defendant joined the conspiracy thirteen years after inception); *Dextone Co. v. Bldg. Trades Council*, 60 F.2d 47, 48 (2d Cir. 1932) ("[E]very person who participates in a conspiracy is liable for everything done during the period of its existence regardless of the exact time at which he becomes a member or the extent of his participation."); *Myzel v. Fields*, 386 F.2d 718, 738 n.12 (8th Cir. 1967) ("[I]t is well settled even under civil or criminal conspiracy that one who knowingly joins a conspiracy even at a later date takes the conspiracy as he finds it, with or without knowledge of what has gone on before.").

3. Direct communications between each conspirator are not required.

The defendants argue that there can be no conspiracy because the purchasers allege no facts establishing "that the Generic Defendants communicated with each other in advance of entering the settlements, or that the settlements were negotiated together."[211] This is inaccurate and irrelevant.

First, the complaint alleges that the generics communicated through hub Takeda.[212] Takeda shared the key term of the agreements with each generic defendant.[213] It is inconceivable that each generic defendant entered its respective settlement with the identical coordinated delayed entry date not knowing and intending that such agreement would be part of an overarching conspiracy to delay generic entry and deter other would-be competitors.[214]

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[211] Defs.' Joint Mot. Dismiss Br. 27.

[212] Compl. ¶ 252.

[213] Compl. ¶ 252; *see, e.g.*, *In re Coordinated Pretrial Proceedings in Petroleum Prods. Antitrust Litig.*, 906 F.2d 432, 447 (9th Cir. 1990) (communication of information necessary for the conspiracy can come through press releases or other publicly available information and "'the *form* of the exchange . . . should not be determinative of its legality" (quoting Richard A. Posner, *Antitrust Law: An Economic Perspective* 146 (1976)); *see also* U.S. Dep't of *Justice & FTC*, *Horizontal Merger Guidelines* 24 (Aug. 19, 2010), https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf ("Coordinated interaction also can involve a similar common understanding that is not explicitly negotiated but would be enforced by the detection and punishment of deviations that would undermine the coordinated interaction."); *In re Valassis Commc'ns, Inc.*, F.T.C. No. C-4160 (Apr. 19, 2006) (statements made during an earnings conference call that the company was raising prices constituted an invitation to its only competitor to collude); *In re Stone Container Corp.*, 125 FTC 853 (1998) (press releases along with other public and private company plan statements constituted an invitation for competitor collusion).

[214] "[A]cquiescence in an illegal scheme is as much a violation of the Sherman Act as the creation and promotion of one." *United States v. Paramount Pictures, Inc.*, 334 U.S. 131, 161 (1948). Accordingly, each Generic Defendant became a knowing and willful participant in the conspiracy and is responsible for perpetuating its success. *Duplan Corp. v. Deering Milliken, Inc.*, 594 F.2d 979, 982 (4th Cir. 1979) (*per curiam*) ("Where, as here, the [defendants] were knowing participants in a scheme whose effect was to restrain trade, the fact that their motives were different from or even in conflict with those of the other conspirators is immaterial."); *Virginia Vermiculite, Ltd. v. W.R. Grace & Co.*, 156 F.3d 535, 541 (4th Cir. 1998) ("[I]t is sufficient that [defendant], regardless of its own motive, merely acquiesced in the restraint with the knowledge that it would have anticompetitive effects."). Indeed, the "the later agreements" with the subsequently settling generic defendants constitute "overt acts" in furtherance of the conspiracy. Hr'g Tr. at 6, Dec. 11, 2013, *In re Nexium Antitrust Litig.*, No. 12-md-02409 (D. Mass.), ECF No. 668.

Under these pre-discovery circumstances, it is entirely plausible to infer a "meeting of the minds."[215]

Second, the law imposes no direct communication requirement.[216] Direct communication was unnecessary because the defendants were well aware of agreements' anticompetitive purpose and understood the benefits to coordination and manipulation of the patent certifications (and the disadvantages of being left on the sidelines).

Third, although coordination clauses may appear "at first blush" to benefit consumers by accelerating entry, this is a mirage.[217] Basic economics reached this conclusion long ago in a variety of analogous contexts, such as most favored nation clauses ("MFNs"), best-price provisions, and the like – all of which appear to benefit consumers by requiring lower prices but in fact can be used anticompetitively to raise prices.[218] The Chairman and CEO of Apotex, Inc., at the time the nation's fifth largest generic manufacturer, decried their use in testimony before Congress:

> [N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. *Consumers are the biggest losers under this system.* . . . .

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[215] *Apple*, 791 F.3d at 318 (concluding that the near-simultaneous signing of separate but materially identical bi-lateral agreements sufficiently established the conspiracy's "meeting of the minds").

[216] *Masonite Corp.*, 316 U.S. at 274-75 (holding conspiracy established where conspirator-spokes knew of the operative terms of each other's agreement with the conspirator-hub notwithstanding that none of the conspirator-spokes communicated with each other); *cf. United States v. Gypsum Co.*, 33 U.S. 364, 394 (1948) ("[W]hen a group of competitors enters into a series of separate but similar agreements with competitors or others, a strong inference arises that such agreements are the result of concerted action.").

[217] *Id.* at 218.

[218] *See, e.g., United States. v. Apple, Inc.*, 952 F. Supp. 2d 638, 694 (S.D.N.Y. 2013) (MFN did not "promote competition, but destroyed it"), *aff'd* 791 F.3d 290, 315 (2d Cir. 2015); *see also Blue Cross & Blue Shield of Ohio v. Bingaman*, No. 94 CV 2297, 1996 WL 677094, at *4 (N.D. Ohio June 24, 1996) ("MFN clauses could violate the Sherman Act by restraining competition."), *aff'd sub nom. Blue Cross & Blue Shield of Ohio v. Klein*, 117 F.3d 1420 (6th Cir. July 11, 1997); *Reazin v. Blue Cross & Blue Shield of Kan.*, 663 F. Supp. 1360, 1418 (D. Kan. 1987) (MFNs "[can] effectively prevent[] competing insurance companies from offering more favorable insurance rates to consumers."), *aff'd*, 899 F.2d 951 (10th Cir. 1990);*United States v. Med. Mutual of Ohio*, No. 98 CV 2172, 1999 WL 670717, at *12 n.6 (N.D. Ohio Jan. 29, 1999) (the proposition that MFNs are procompetitive as a matter of law "soundly rejected").

> . . . . These "poison pills" undermine the incentive of subsequent filers to carry on the patent fight and empower first filers to accept later entry dates. Acceptance of later entry dates in settlements is possible because the "poison pill" guarantees the first filer's ability to retain exclusivity no matter how long the period of delay it agrees to is.[219]

Consider the Second Circuit's decision in *Apple*.[220] Apple sought to offer a competitive alternative to the Kindle through the launch of its iPad and iBookstore, and negotiated separate bi-lateral agreements with six market-dominating book publishers. Each agreement was executed near in time to each other and contained materially identical terms, including the same MFN that set high e-book prices but left each book publisher less profit than if they had sold the same e-book through Amazon. Each publisher knew that the other publishers were given the same MFN. The economic effect was to make "it imperative, not merely desirable" that the publisher defendants renegotiate their Amazon agreement in order to increase overall market prices and overall long-term gains (which would more than offset any short-term revenue sacrifice from the Apple deal).[221] The Second Circuit held that the separate bilateral agreements themselves, even if not independently unlawful, "in context . . . provide[d] strong evidence that Apple consciously orchestrated a conspiracy among the Publisher Defendants."[222] This was because each agreement was "attractive" to each of the publisher defendants only if they "acted collectively" and "in tandem."[223] The Court further held that execution of that

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[219] *H.R. 1706, The Protecting Consumer Access to Generic Drugs Act of 2009: Hearing Before the Subcomm. on Commerce, Trade & Consumer Protection of the H. Comm. on Energy & Commerce*, 111th Cong. 218, 226 (2009) (statement of Dr. Bernard C. Sherman, CEO, Apotex Inc.).

[220] 791 F.3d 290.

[221] *Id.* at 304-05.

[222] *Id.* at 316.

[223] *Id.*

bilateral agreement constituted each publisher defendants' ratification of its joinder in the conspiracy.[224]

A similar result should be reached in this case. Like *Apple*, Takeda orchestrated, and each generic ratified, the conspiracy. Since the materially identical clauses are a form of a most favored nation's clause that, if hypothetically triggered, would work to the disadvantage of the party granting the MFN, then the grant must in some way also be working to the advantage of the brand.[225] Thus, the coordination clauses, paragraph IV certification requirement, and delayed entry date work in unison to push back generic entry and result in higher prices paid by consumers by further reducing the incentive of other generic manufacturers to continue challenging the patent.[226]

4. Agreeing to delay generic entry until August 17, 2012 contravened each generic defendant's economic self-interest, but that agreement was made attractive because each was assured that no other generic manufacturer would enter the market first.

Takeda faced challenges to its patent from each of the generic defendants. To eliminate those challenges, Takeda needed to reach a resolution with all of them. The identical terms that Takeda employed to facilitate these settlements reflects the economic reality that it was contrary to each generic defendant's economic self-interest to agree to stay off the market if the other generics did not also agree to the same delayed entry date and have the assurance, provided by the coordination clause, that no other generic would be able to leap-frog its generic to market ahead of the participating generic defendant. Thus, Takeda, acting as the go-between, was able to orchestrate an agreement between the generic defendants not to compete with each other and thereafter police the conspirators. Without the coordination clause,

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[224] *Id.* at 317-18.

[225] Compl. ¶¶ 261-62.

[226] C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity*, 77 Antitrust L.J. 947, 964 (2011).

paragraph IV certification requirement, and delayed entry date, each generic defendant – operating pursuant to its independent economic self-interest – would have sought the earliest possible entry date without regard to what its fellow generics (its competitors) had agreed to, either by litigating the patent suit to conclusion, or otherwise.

Toys "R" Us v. FTC[227] is especially instructive. In *Toys "R" Us*, several toy manufacturers entered into agreements with Toys "R" Us agreeing not to sell certain toys to the retailer's competitors, specifically warehouse clubs.[228] The court observed that "each manufacturer was afraid to curb its sales to the warehouse clubs alone, because it was afraid its rivals would cheat and gain a special advantage."[229] Because "the only condition on which each manufacturer would agree to [the retailer's] demands was if it could be sure its competitors were doing the same thing," Toys "R" Us "assure[d] individual manufacturers that no one would be singled out" and then "served as the central clearinghouse for complaints about breaches in the agreement."[230] And the Seventh Circuit held: "*That is a horizontal agreement.*"[231]

Here, the generic defendants faced the same competitive dilemma that confronted the toy manufacturers in *Toys "R" Us* – each agreed to delay generic entry only on the condition that its competitors would do the same thing. The delayed entry date and coordination clause provided the protection each generic needed to assure it that its competitors could not come to market earlier. And while Toys "R" Us was "careful to meet individually with each of its suppliers to explain its new policy" and separately negotiate the agreements,[232] such formalistic solicitude does not immunize the collusive conduct that was actually at work.

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[227] 221 F.3d 928 (7th Cir. 2000).

[228] *Id.* at 931-32.

[229] *Id.* at 936.

[230] *Id.* at 933, 936.

[231] *Id.* (emphasis added).

[232] *Id.* at 932.

Faced with a substantially similar coordination clause among generic defendants, the court in *Nexium II* held that "[d]elayed entry, not contingent launch, is the substance of each settlement agreement, and the actual concession for which [the brand manufacturer] allegedly paid valuable consideration."[233] The court framed the issue as "whether it was [in the best interest] for each generic manufacturer to agree to delay entering the generic market" rather than whether it was in the generic defendants' best interests to accept the benefits of the conspiracy, which it obviously was.[234] In answering that question, the court viewed the existence of the coordination clause as evidence that agreeing to delay entry was against the settling generics' economic self-interests:

> The unattractiveness of being "stuck on the sidelines" . . . meant that to each Generic Defendant, delayed entry on its own was not a viable proposition unless it could be assured of its position vis-a-vis its competitors. This dilemma set up a clear incentive for the Defendants to cooperate with each other, and they did so by providing for contingent launch clauses that would coordinate the Generic Defendants' entries into the market.[235]

Here, the coordination clause (operating with the paragraph IV requirements, delayed entry date, and faux-secrecy provision), as *Nexium II* recognized, is simply the mechanism by which the brand "assured" each settling generic defendant that the other generic defendants would agree to the same terms.[236] These facts are no different than the situation faced by the parties in *Toys "R" Us* and *Nexium*, where all competitors agreeing to the same terms provides the "rim" necessary for a hub-and-spoke conspiracy.[237]

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[233] 42 F. Supp. 3d at 257.

[234] *Id.*

[235] *Id.*

[236] *Id.* at 257-58.

[237] *Id.* ("From the fact that the Nexium settlement agreements were not in the generic defendants' self-interest unless their agreements contained provisions aligning their behavior, a reasonable fact-finder could draw an inference of conspiracy."). Defendants ignore *Toys "R" Us* and *Nexium II*, and instead rely on the summary judgment decision in *King Drug Co. of Florence v. Cephalon, Inc.*, 2:06-cv-1797, 2014 U.S. Dist. LEXIS 84818 (E.D. Pa. June 23, 2014). Joint Mot. Dismiss Br. 28-29 & n.10. In *King Drug*, at the pleading stage, the Court upheld

5. The defendants had strong motivations to coordinate their actions.

Takeda and the generic defendants had a strong motive to conspire. Sales of ACTOS in the United States alone approximated $3 billion; hundreds of millions of dollars in sales awaited the first generic market entrant.[238] To prevent the loss of these sales and profits, Takeda conspired with its would-be competitors.

The first wave generics shared an additional motive. Each knew that settling on those terms effectively preserved the false 180-day ACTOS exclusivity; that reality, coupled with Takeda's promise not to launch a competing authorized generic during the 180-day exclusivity, assured that the generic defendants could charge competition-free prices during that period. The exclusivity period generates the "vast majority" of the first-filer's profits.[239] A first-filer "is therefore much more willing to accept a later entry date than it would be if settlement did not preserve exclusivity."[240] A result that conforms to standard economic analyses.[241]

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similar coordination clause-predicated overarching conspiracy allegations and denied defendants' motions to dismiss. *See King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 532-33 (E.D. Pa. 2010). In its summary judgment decision, however, the court employed a faulty analysis and consequently veered off course. Rather than assess the generic defendants' economic self-interest motivations and options absent the anticompetitive conduct, the court instead put its thumb on the scale by including in its analysis the benefit of the conspiracy bargain – "lucrative business deals and an assurance that each Generic Defendant would not be disadvantaged regarding the entry of generic Provigil." 2014 U.S. Dist. LEXIS 84818, at *57-58. The benefits obtained as a result of a conspiracy bargain are of course – as *Nexium II* aptly observed – in the economic self-interest of the conspirator-participant. The proper analysis, however, requires consideration of the generic defendants' economic self-interests absent the conspiracy bargain. Coordination of each generic defendant's entry coupled with the assurance that no other generic could enter the market any sooner are *advantages that neither the Hatch-Waxman Act nor successful litigation of the patent could provide.* Each generic defendant should have sought to beat its generic competitors to market at the earliest possible date. Any agreement to the contrary contravenes the generic competitor's economic self-interest. *Nexium II*, 42 F. Supp. at 256 ("The record – and common sense – also shows that each Generic Defendant would be reluctant to agree to delay its entry unless [the brand manufacturer] could secure the same guarantee of delay from all its generic competitors, lest a competitor capture the generic market before [the agreed upon entry date]." (internal citation omitted)).

[238] Compl. ¶¶ 5, 266.

[239] *Actavis*, 133 S. Ct. at 2229.

[240] C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1593 (2006) ("[e]njoying the exclusivity period with certainty is more important to a generic firm than its timing").

[241] *See, e.g., United States v. Blue Cross Blue Shield of Mich.*, 809 F. Supp. 2d 665, 669 (E.D. Mich. 2011) (defendant is willing to pay higher prices to hospitals in exchange for MFN because of its tendency to preserve defendant's market share); Steven C. Salop & Fiona Scott Morton, *Developing an Administrable MFN Enforcement*

Teva also understood the anticompetitive effect of the agreements' terms. Teva knew that even if it litigated, won, and entered early, the terms of the agreements would mean that the other generic manufacturers would share in the fruits of Teva's win.[242]

C. The anticompetitive conduct caused antitrust injury.

1. Antitrust causation is a highly fact dependent inquiry.

A defendant is liable for the harm caused by its anticompetitive conduct. "It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury."[243]

According to the Second Circuit, when a defendant's act is "deemed wrongful precisely because it has a strong propensity to cause the type of injury that ensued, that very causal tendency is evidence enough to establish a *prima facie* case of cause-in-fact."[244] The Supreme Court acknowledges that a degree of uncertainty is always permitted, particularly when the wrongdoing created the uncertainty.[245] "[T]he wrongdoer may not object to the plaintiff's reasonable estimate of the cause of injury," grounded in evidence, by arguing that it is "not based on more accurate data which the wrongdoer's misconduct has rendered unavailable."[246]

Policy, 27 Antitrust ABA 15, 16 (2013) (buyer is willing to pay higher price when MFN dampens competition from rivals); Steven C. Salop, Practices that (Credibly) Facilitate Oligopoly Co-ordination, New Developments in the Analysis of Market Structure 265 (Joseph E. Stiglitz & G. Frank Mathewson eds., 1986) (party will accept less competitive terms when MFN injures rivals because party will "count that injury as a benefit").

[242] Compl. ¶ 276.

[243] *Zenith Radio*, 395 U.S. at 114 n.9 (emphasis added); *see also In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 12-md-2343, 2013 WL 2181185, at *16-17 (E.D. Tenn. May 20, 2013) (at early stage of litigation, plaintiffs not required to disprove all possible alternative causes); *In re Neurontin Antitrust Litig.*, MDL No. 1479, 2009 WL 2751029, at *11-12 (D.N.J. Aug. 28, 2009) (same); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) (same).

[244] *Liriana v. Hobart Corp.*, 170 F.3d 264, 271 (2d Cir. 1999).

[245] *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 263-64 (1946) (rejecting defendant's argument that "it is not possible to say what th[e] conditions would have been if the restraints had not been imposed").

[246] *Bigelow*, 327 U.S. at 265.

"Any other rule would enable the wrongdoer to profit by his wrongdoing at the expense of his victim."[247]

Causation is a question of fact, not appropriate for resolution at the motion to dismiss stage. "Causation questions . . . are normally grist for the jury's mill."[248] So at the pleading stage, a plaintiff must simply "present sufficient evidence to support a finding" that, absent the unlawful conduct, a more competitive outcome was "feasible,"[249] even if it "remains unclear" what would have happened if the defendants "had not engaged in [the] conduct."[250]

2. The complaint alleges the wrongful antitrust acts caused harm.

The complaint plausibly links the defendants' wrongful acts to the purchasers' injuries. If Takeda had not wrongfully told the FDA that the '584 and '404 patents included product claims covering ACTOS, then no false exclusivity for ACTOS generics would have existed. Takeda took advantage of the regulatory scheme and caused the FDA's predictable regulatory actions that created false exclusivities. In the absence of Takeda's misrepresentations, the generics' section viii statements to the method of use claims would have allowed them to come to market once the original '777 patent expired in January 2011.[251] The FDA had already granted Teva tentative approval on February 7, 2006; only the '777 patent stood in Teva's way. Teva is the world's largest generic drug manufacturer; ACTOS is not difficult to make (as evident from the large number of ANDA filers and tentative approvals); Teva would have been motivated to enter quickly in order to start earning revenue from ACTOS sales; and Teva has repeatedly entered generic markets at the soonest opportunity following FDA ANDA

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[247] *Id.* at 264.

[248] *Peckham v. Cont'l Cas. Ins. Co.*, 895 F.2d 830, 837 (1st Cir. 1990).

[249] *Sullivan v. NFL*, 34 F.3d 1091, 1104 (1st Cir. 1994).

[250] *Irvin Indus., Inc. v. Goodyear Aerospace Corp.*, 974 F.2d 241, 246 (2d Cir. 1992).

[251] Compl. ¶¶ 351-52

approval.[252] A reasonable generic company in Teva's position would have entered immediately following FDA approval.[253]

The forces of industry practice, applied microeconomics, the law on induced infringement claims, and common sense all teach that generics would have entered on or shortly after January/February 2011 for both ACTOS and ACTO*plus* met, and certainly earlier than the entry dates provided by the March and December 2010 pacts.

3. It is what Takeda told the FDA, not what the generic defendants read in the Orange Book, that caused injury.

Takeda claims that the paragraph IV certifications at issue were not caused by Takeda's falsely describing its patents to the FDA because the false descriptions were not made public until 2010.[254]

Until August 2003, the FDA's technological limitations prevented the Orange Book from showing a single patent as including more than one "type" of claim.[255] But despite the historic notice limitation, however, FDA regulations and instructions made unmistakably clear that it is the *patent information* submitted by the NDA applicant (not the notice of it presented in the Orange Book) that governs *the FDA's determination* as to how reported patent claim information impacts the timing and conditions for FDA approval.[256]

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[252] Compl. ¶ 352.

[253] *Id.*

[254] Takeda Br. 10-11.

[255] *See* FDA/CDER Resp. Sandoz, Inc. Citizen Pet., Docket No. FDA-2009-P-0411-0010 (Mar. 15, 2010), at 2.

[256] *See, e.g.*, *Abbreviated New Drug Application Regulations*, 54 Fed. Reg. 28,872, 28,885 (proposed July 10, 1989) ("[T]he patent information submitted to FDA, whether or not published in the list, should be the basis of the [generic company's] certification."); 21 C.F.R. § 314.94(a)(12)(iii) (ability to submit only a section viii statement is based on "patent information . . . submitted under . . . § 319.53"). As the Supreme Court recognized, "'Patent information submitted . . . under subsection (b) or (c)' most naturally refers to patent information provided as part of the comprehensive scheme of regulation premised on those subsections;" "the word 'under' naturally reaches beyond that most barebones information to other patent materials the FDA demands in the regulatory process." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1684, 182 L. Ed. 2d 678 (2012) (internal citation and quotation omitted).

Takeda knows that its false submissions control FDA's actions, not the generics. In its response to the Sandoz citizen petition, it wrote the FDA that what should control is its characterization of the patents, not anything that the generics said or did. The relevant inquiry is not whether the generic defendants read Takeda's (false) submissions. Rather, the focus is on the predictable anticompetitive effect that Takeda's misleading submissions had on the FDA's ANDA approval and exclusivity processes.

4. Generic ANDAs with carved-out labels would have been readily approved.

The Supreme Court in *Caraco* wrote: "Congress understood that a drug may have multiple methods of use, not all of which a patent covers; and a section viii statement allows the FDA to approve a generic drug for unpatented uses so that it can quickly come to market."[257] Section viii, the Court pointed out, "provides the mechanism for a generic company to identify [particular unpatented uses of a drug], so that a product with a label matching them can quickly come to market. The statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones."[258]

The defendants argue that, even if Takeda had told the FDA the truth, it is unclear whether generics would have chosen the section viii approach to the '584 and '404 patents, as opposed to an optional paragraph IV route.[259] But this ignores the law and regulations.

The generic defendants filed ANDAs that proposed labels that carved out combination use of ACTOS.[260] FDA regulations prohibit applicants from both carving out a use and

[257] *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1673 (2012).

[258] *Id.* at 1681-82.

[259] Takeda Br. 10-12.

[260] *See., e.g.*, Mylan's Pretrial Br., 2005 U.S. Dist. Ct. Motions LEXIS 27367, at *30; *Sebelius*, 2012 WL 6968224, at *4; Mem. Supp. Teva's Mot. Add Counterclaim 4, *Takeda Pharm. Co. Ltd. v. Teva Pharm. Indus. Ltd.*, No. 09-cv-4665 (S.D.N.Y Mar. 30, 2010), ECF No. 49.

submitting a paragraph IV certification for the same use claims.[261] As a result, without a product claim listing and with their carved out labels, the *generics would have had no choice* but to file *only section viii statements* with respect to the '584 and '404 patents.

Nor does it make any sense for the defendants to speculate that, without a product claim listing, the generics would have withdrawn carved-out labeling to then pursue approval for the combination uses – all the generics pursued section viii statements for the use claims, and nothing about the absence of a product claim listing would bear on the sensible economic decision to pursue early market entry with a section viii carve-out.

Takeda also throws against the wall the argument that the FDA might not have approved a generic ANDA for ACTOS containing a section viii statement because the FDA might have found that to be a safety risk.[262] The generic co-defendants do not join Takeda on this one, as they know it is specious.

None of the defendants contest that the generic defendants' products were therapeutically equivalent to ACTOS. In fact, *the FDA gave tentative approval* to the Mylan, Actavis and Teva ANDAs with section viii statements and labeling providing for use of pioglitazone as monotherapy.[263] Tentative approval by the FDA means that an ANDA meets

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[261] As the FDA has explained, "an ANDA applicant does not have the option of choosing between a paragraph IV certification and a section viii statement where the patent claims only a method of use; where the labeling does not include [the method of use], only the section viii statement is appropriate." Compl. ¶ 188 n.33.

[262] Takeda relatedly argues that count 1 fails because the complaint does not identify a particular generic company that would have obtained earlier approval based on a section viii request. To the contrary, the complaint alleges that absent Takeda's wrongful conduct, the generic defendants themselves would have obtained approval based on such a request. *See, e.g.*, Compl. ¶¶ 168, 174, 351-52.

[263] Mylan submitted its ANDA in July 2003 with section viii statements addressing the composition claims of the '584 and '404 patents and paragraph IV certifications for the method of use claims, *Sebelius*, 2012 WL 6968224, at *7, *10, and Mylan's proposed labeling carved out uses of its generic product with metformin or any other antihyperglycemic agent. *See, e.g.* Mylan's Pretrial Br., 2005 U.S. Dist. Ct. Motions LEXIS 27367, at *30 ("Mylan's labeling omits any statement or suggestion that Mylan's products can be used in a way that would infringe Takeda's Combination Patents, i.e., in combination drug therapy."). The FDA gave tentative approval to Mylan's ANDA, including the proposed labeling, on November 3, 2004. *See* FDA Approval History for Pioglitazone Hydropchloride, ANDA No. 076801, http://1.usa.gov/1SbVqJo (last visited Mar. 21, 2016). Actavis submitted section viii statements for the '584 and '404 patents and proposed labeling limited to monotherapy, and the FDA gave Actavis's ANDA tentative approval on December 13, 2005. *Sebelius*, 2012 WL 6968224, at *4-7,

the requirements for final approval, including bioequivalence to the RLD and labeling; there only remains some statutory or regulatory exclusivity.[264] Those substantive requirements include not only scientific information, but also the adequacy of the labelling.[265] Thus, the FDA's tentative approval of the ANDAs showed that the preconditions for acceptable labelling – including the determination needed for the section viii carve outs that no safety or efficacy issue arose from them – shows the plausibility of the FDA's acceptance of the generic companies' section viii statements.

The FDA has articulated its approach to accepting proposed labels that carve out combination use. It emphasizes that brand efforts to restrict access to non-patented uses is contrary to the regulatory scheme.[266]

> Under [the brand's] interpretation of the misbranding provisions, the existence of patent protection for Camptosar's first-line indication or any combination use *would prohibit the approval of a generic irinotecan product for any indication for the duration of the patent on the use of the drug in combination*, thereby limiting the opportunity for consumers to benefit from the existence of lower-cost generic products, *even for the non-protected . . . use of the product as monotherapy*, during this period. On the

*10. Teva also submitted section viii statements for the '584 and '404 patents, and the FDA gave tentative approval to Teva's ANDA on February 2, 2006. Mem. Supp. Teva's Mot. Add Counterclaim at 4, *Takeda Pharm. Co. Ltd. v. Teva Pharm. Indus. Ltd.*, No. 09-cv-4665 (S.D.N.Y Mar. 30, 2010), ECF No. 49 ("Teva filed section viii statements to [the '584 and the '404 patents] indicating that Teva will not include language in the label for its proposed generic version of Actos® that refers to combination use, and thereby that Teva's product will not practice the method-of-use claims of the '584 and the '404 patents."); *id.* at 5 ("On February 7, 2006, the FDA granted tentative approval to Teva's ANDA.").

[264] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); 21 CFR § 314.127(a)(7) ("FDA will refuse to approve" an ANDA if "[i]nformation submitted in the [ANDA] is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the [RLD] *except for changes required* because of differences approved in a petition under § 314.93 or because the drug product and the [RLD] are produced or distributed by different manufacturers or *because aspects of the listed drug's labeling are protected by patent, or by exclusivity*, and such differences do not render the proposed drug product less safe or effective than the listed drug for all remaining, nonprotected conditions of use." (emphasis added)). As Mylan noted in the underlying patent litigation, "[a]n FDA 'tentative approval' means that all of the regulatory requirements for Mylan's ANDA have been satisfied and that the product can be marketed by the ANDA applicant in the United States once certain events outside of FDA's control have occurred, such as resolution of this patent infringement action in Mylan's favor." Mylan's Pretrial Br. Combination Patents, *Takeda Chem. Indus. v. Mylan Labs., Inc.*, No. 03-CV-8253, 2005 U.S. Dist. Ct. Motions LEXIS 27367, at *34 (S.D.N.Y. Dec 2, 2005).

[265] 21 U.S.C. § 355(j)(2)(A) (listing requirements for an approvable ANDA).

[266] *See* FDA/CDER Resp. Watson Labs., Inc. Citizen Pet., Docket No. FDA-2008-P-0069, at 1 (July 28, 2008).

> other hand, our interpretation allows innovators to enjoy the benefits associated with their efforts to develop new indications (including patent protection and exclusivity for those indications) while promoting competition with respect to indications for which innovators are not entitled to protection (either because they have not conducted research that entitles them to protection *or because any applicable protection has expired, been successfully challenged, or has otherwise ceased to be a barrier to approval*).[267]

Finally, Takeda's speculation that a generic company that obtained approval of a carved-out label would not have launched its product[268] cannot be seriously entertained. The defendant Teva's statements to the federal court – that it had every expectation to launch its product by the end of January 2011 – are enough to reject that bit of Takeda speculation.

5. Takeda's induced infringement litigation would not bar generic entry.

Section 271(b) of the Patent Act provides that "whoever *actively* induces infringement of a patent shall be liable as an infringer."[269] In 2003, when Takeda sued the first filers for infringement, the law provided that filing an ANDA that carved out patented uses did not amount to induced infringement:

> [T]he request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA does not induce anyone to perform the unapproved acts required to infringe. That a generic maker may someday induce someone to infringe can only be determined when that act occurs, and § 271(e)(2) was not designed to cover such future acts.[270]

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[267] *Id.* (emphasis added). This reasoning is in keeping with the Hatch-Waxman Act's aim of getting generics to market quickly. *See, e.g., Burwell*, 82 F. Supp. 3d at 198 ("The FDA's interpretation . . . is entirely in keeping with . . . the larger Hatch-Waxman goal of streamlining generic drug approvals to allow safe, effective generic drugs to reach the market sooner.").

[268] Takeda Br. 14-16.

[269] 35 U.S.C. §271(b)(emphasis added).

[270] *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364-65 (Fed. Cir. 2003); *see also Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1332 (Fed. Cir. 2003).

Takeda acknowledged that "the mere sale of a product capable of substantial noninfringing uses does not constitute indirect infringement of a patent . . . [unless] active steps are taken to encourage direct infringement."[271]

The Federal Circuit holds that inducement requires proving both "specific intent" and "action to induce infringement."[272] Judge Cote recognized this standard in the Rule 12(b)(6) decision in the *Watson* litigation:

> Mere knowledge of the allegedly infringing acts is not sufficient to show inducement; there must be proof of actual intent to cause the infringing activity. Such proof may be in the form of direct or circumstantial evidence.[273]

So Takeda's only hope of prevailing on its induced infringement claims was to show that the generics had specific intent and had actually taken actions to induce infringement. But the best Takeda could muster was a general allegation "on information and belief."

As a matter of law, these rote allegations would not carry the day at summary judgment or trial. Particularly not where each of the generics alleged that they had not, and would not, undertake action to induce infringement. As Mylan stated in its pretrial brief:

> . . . . Mylan has engaged in no affirmative activity that encourages, aides or abets anyone to use Mylan's products in such a way, and there is no evidence that Mylan will, in the future, engage in such activity.[274]

Takeda has said nothing to rebut this. And even if Takeda had somehow prevailed in proving induced infringement against one of the generics, the relief granted would only have

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[271] *See* Mylan's Second Pretrial Br., *Takeda Chem. Indus. v. Mylan Labs., Inc.*, No. 03-cv-8253, 2005 U.S. Dist. Ct. Motions LEXIS 27366, at *9 (S.D.N.Y. Dec. 2, 2005) (quoting Takeda's Pre-Trial Mem. Combination Patents at 20).

[272] *Id.*

[273] *Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc.*, 329 F. Supp. 2d 394, 401 (S.D.N.Y. 2004) (internal citation omitted).

[274] Mylan's Pretrial Br. Combination Patents, *Takeda Chem. Indus. v. Mylan Labs., Inc.*, No. 03-CV-8253, 2005 U.S. Dist. Ct. Motions LEXIS 27367, at *12-13 (S.D.N.Y. Dec 2, 2005).

been an injunction preventing the generic from continuing the inducing activities, not preventing the infringing generic from coming to market.

Under patent law, an injunction may extend only as far as is necessary "to prevent the violation of any right secured by the patent."[275] Where a patentee seeks an injunction to prevent induced infringement, the scope of injunctive relief is "modest" – limited to enjoining an alleged infringer from "actively inducing infringement" of the patent in suit.[276] An injunction for induced infringement cannot bar, outright, the sale of a product capable of infringing a method-of-use patent, where the product is capable of other uses; such injunctive relief "would impermissibly expand the scope of [a] patent monopoly by effectively granting [the patentee] a monopoly over a product capable of noninfringing uses."[277]

The defendants cite *AstraZeneca LP v. Apotex, Inc.*,[278] to argue that inducement charges can yield relief enjoining a generic product from the market.[279] But the facts there are so unique, a different lesson emerges. AstraZeneca held two patents covering a method of using budesonide once daily.[280] Apotex sought to "carve out" once-daily use, but for safety reasons the FDA required Apotex to include in its label an instruction that patients be "titrated down"

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[275] 35 U.S.C. § 283.

[276] *See, e.g., U.S. Philips Corp. v. Iwasaki Elec. Co. Ltd.*, 607 F. Supp. 2d 470, 483-84 (S.D.N.Y. 2009) (noting patentee sought "an array of injunctive provisions," but limiting injunctive relief to a prohibition on inducing infringement.).

[277] *See, e.g., Mickowski v. Visi-Trak Corp.*, 36 F. Supp. 2d 171, 182 (S.D.N.Y. 1999) (citing *Rohm & Haas Co. v. Dawson Chem. Co.*, 599 F.2d 685, 703 n.24 (5th Cir. 1979)) (granting, instead, an injunction limited to prohibiting "further publication or distribution of any product manual, sales literature, or other instructional or promotional materials" describing how defendants products "may be used to practice the methods taught by claim 1 and claim 28 of the patents in suit"); *see also Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774-76 (Fed. Cir. 1993) (vacating injunction as overbroad because mere sale of equipment, which could be used to perform a process protected by patentee's patent, did not constitute induced infringement); *id.* at 775 ("[T]he act of selling equipment which will not be used so as to directly infringe a method claim cannot constitute one of the dependent types of infringement, that is, either contributory infringement or inducement of infringement.").

[278] 633 F.3d 1042 (Fed. Cir. 2010).

[279] Joint Br. 23-24.

[280] *AstraZeneca*, 633 F.3d at 1046-47.

to the lowest possible dose, *i.e.*, to once-daily use.[281] The required labelling "would inevitably lead some consumers to practice the claimed method."[282] So the only example the defendants can show is when the FDA insists on labelling that will *require* doctors to engage in the patented use.

Here, in contrast, the FDA sought no change to the carve outs, and there is nothing in the proposed labels that would *require* a physician to prescribe ACTOS in combination with another drug. Physicians could simply prescribe ACTOS as monotherapy. The fact that some physicians might combine ACTOS with biguanide or a sulfonylurea is not enough to establish induced infringement[283] – *AstraZeneca* teaches that the infringement must be "inevitabl[e]."[284] The defendants here are trying to accomplish that which Judge Cote warned about – extending broad patent protection using only patents applicable to particular uses.

The Federal Circuit previously admonished Takeda that it cannot enjoin a competitor's launch by claiming induced infringement – especially where Takeda offers nothing more than a suggestion of its competitor's "mere knowledge of infringing uses" by doctors.[285] In *Mitigare*, Takeda held patents claiming a method of using colchicine products to treat acute gout flares.[286] Another company, Hikma, launched a colchicine product for gout prophylaxis.[287] Takeda sued, asserting induced infringement claims.[288] The district court denied Takeda's motion for a preliminary injunction, and the Federal Circuit affirmed. The Federal Circuit

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[281] *Id.* at 1047.

[282] *Id.* at 1060.

[283] *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.* ("*Mitigare*"), 785 F.3d 625, 630-32 (Fed. Cir. 2015) (affirming denial of injunction).

[284] *AstraZeneca*, 633 F.3d at 1060.

[285] *Mitigare*, 785 F.3d at 630.

[286] *Id.* at 627.

[287] *Id.* at 628.

[288] *Id.*

explained there is no induced infringement "'when a defendant merely sells a commercial product suitable for some lawful use.'"[289] Merely selling a drug product that might be used by physicians for an infringing use does not transform a drug maker into an infringer – "[t]he label must encourage, recommend, or promote infringement."[290] Induced infringement requires "specific intent and action," and this requirement is "particularly important in the Hatch-Waxman Act context because the statute was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses."[291] The Federal Circuit agreed with the district court that Takeda had no likelihood of success on the merits of its suit.[292]

Takeda is left to making the argument that, no matter how wildly unlikely it would have been for a court to enjoin every one of the generics' ACTOS launches (and not just their arguable inducing conduct), that remote chance is enough to bar recovery because courts never predict the outcome of lawsuits. Not true.

The Supreme Court recently acknowledged the common need to prove a "case within a case." In *Gunn v. Minton*,[293] the Court stated:

> In cases like this one, in which the attorney's alleged error came in failing to make a particular argument, the causation element requires a 'case within a case' analysis of whether, had the argument been made, the outcome of the earlier litigation would have been different . . . . To prevail on his legal malpractice claim, therefore, Minton must show that he would have prevailed in his federal patent infringement case if only petitioners had timely made an experimental-use argument on his behalf.[294]

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[289] *Id.* at 630 (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005)).

[290] *Id.* at 631. In *Mitigare*, Takeda conceded that "mere knowledge of off-label infringing uses of [a] product would not establish inducement." *Id.* at 632.

[291] *Id.* at 631.

[292] *Id.* at 632-34.

[293] 133 S. Ct. 1059 (2013).

[294] *Id.* at 1065 (internal citations omitted).

The need to evaluate what would have happened is especially salient in the antitrust context. "Every [antitrust] case involves a comparison of a challenged agreement against a prediction about – a probabilistic assessment of – the expected competition that would have arisen in its absence."[295] A defendant cannot "complain of an uncertainty created by his own wrongdoing,"[296] and "may not object to the plaintiff's reasonable estimate of the cause of injury" by arguing that it is "not based on more accurate data which the wrongdoer's misconduct has rendered unavailable."[297] "Any other rule would enable the wrongdoer to profit by his wrongdoing at the expense of his victim."[298]

Under the Supreme Court's decision in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*,[299] antitrust cases involving sham litigation as the anticompetitive act require a plaintiff to prove that the patentee's infringement claims were "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits."[300] By definition, the plaintiff must postulate and prove the results of the litigation – that the patentee would have lost and the challenger would have won. Plaintiffs may not simply guess, of course; rather, a plaintiff must "present sufficient evidence to support a finding"[301] that, absent the unlawful conduct, a different and more competitive outcome was "feasible."[302]

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[295] *In re Cipro Cases I &II*, 348 P.3d 845, 864 (Cal. 2015).

[296] *Jay Edwards, Inc. v. New England Toyota Distrib., Inc.*, 708 F.2d 814, 821 (1st Cir. 1983) (quoting *Randy's Studebaker Sales, Inc. v. Nissan Motor Corp.*, 533 F.3d 510, 517 (10th Cir. 1976)).

[297] *Bigelow*, 327 U.S. at 265

[298] *Id.* at 264.

[299] 508 U.S. 49, 60 (1993).

[300] *Id.* at 60.

[301] *Sullivan*, 34 F.3d at 1103.

[302] Id. at 1104.

Takeda argues, in effect, that all antitrust claims based on patent settlements must fail, as there will never in those cases be a final adjudication of the patent litigation. This is not the law.[303]

"No government seriously concerned about the evil of monopoly" would permit an antitrust violator to escape liability merely by arguing that proving what would have happened is too speculative.[304] "Doubts should be resolved against the person whose behavior created the problem."[305] Takeda makes no showing, under either the law or the allegations, that an injunction enjoining wholesale launch of every one of the proposed generic products was such a feasible possibility that the purchasers will need to disprove it.

6. The FDA's two month delay in approving the Actavis ANDA does not warrant dismissing Actavis.

Actavis argues that it could not have launched its generic product any earlier than October, 2012 because it was not until that time that the FDA granted it final approval.[306]

Although an antitrust plaintiff need only prove that a defendant's antitrust violation is a "material cause" of its injury, "[o]n occasion . . . an independent cause [that] fully accounts for the plaintiff's alleged injury . . . breaks the causal connection."[307] But it is the *defendant's burden* to establish "the existence of an independent cause" that destroys antitrust causation,[308] as

[303] *See In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 691 (2d Cir. 2009) (rejecting the argument that "direct purchasers would be able to recover antitrust damages from a fraudulent patentee *only* after that patentee first loses on a fraudulent procurement claim").

[304] III Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 651(c) (2d ed. 2000).

[305] *Id.*

[306] Teva/Actavis Br. 19-22.

[307] *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 756 (E.D. Pa. 2003).

[308] *Id.*; *see also Carlson v. Chisholm-Moore Hoist Corp.*, 281 F.2d 766, 770 (2d Cir. 1960) (A plaintiff is not required to "'offer evidence which positively exclude[s] every other possible cause of the accident.'" (quoting *Rosenberg v. Schwartz*, 183 N.E. 282, 283 (N.Y. 1932))).

numerous federal circuits have indicated.[309] This concept flows naturally from basic tort-law principles: "a 'superseding cause' (something that intervenes between the defendant's wrongful act and the plaintiff's injury, 'snap[ping] the causal chain' that links the act to the injury) can 'wip[e] out the defendant's liability' – but the burden of proving this 'is on the defendant.'"[310] And whether the occurrence – or non-occurrence – of some FDA regulatory action "constitutes intervening conduct that breaks the chain of causation and whether intervening conduct is a foreseeable consequence of a defendant's actions are questions of fact to be submitted to the jury."[311] We do not have to plead the absence of Actavis's affirmative defenses.

And the argument falls flat on the facts. Under the March 2010 pact, Actavis and Mylan agreed to amend their ANDAs to add paragraph IV certifications for all use patent claims. Mylan did so promptly; Actavis waited two years to do so. As a result, on the eve of the eventual August 2012 generic ACTOS entry, Actavis found itself in a bit of a tussle with the FDA over whether Actavis had lost its shared first-to-file status with Mylan. After a brief court proceeding, Actavis got the preferred status reinstated, and launched two months late (in October 2012).

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[309] *See, e.g.*, *Hill v. Reederei F. Laeisz G.M.B.H.*, 435 F.3d 404, 421 (3d Cir. 2006) (As to "superseding cause, the defendant has the burden of proof by a preponderance of the evidence."); *Hasbrouck v. Texaco, Inc.*, 842 F.2d 1034, 1042 (9th Cir. 1987); *Carlson*, 281 F.2d at 770.

[310] *In re Goguen*, 691 F.3d 62, 68 (1st Cir. 2012) (quoting *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 757 (7th Cir. 2011) (Posner, J.)); *see also In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 45 (1st Cir. 2013) ("[T]he burden of proving an 'intervening cause' . . . is on the defendant."); *In re Aggrenox Antitrust Litig.*, No. 14-md-2516, 2015 WL 4459607, at *10 (D. Conn. July 21, 2015) ("The defendants can certainly defend themselves in this case by arguing that generic entry for one reason or another would have been impossible at any particular time even in the absence of the agreement.").

[311] *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619 (E.D. Pa. 2011) (denying summary judgment where defendants argued that the FDA's arguments, and not the drug companies' conduct, caused generic delay); *see Exxon Co., USA v. Sofec, Inc.*, 517 U.S. 830, 840-41 (1996) ("The issues of proximate causation and superseding cause involve application of law to fact, which is left to the factfinder, subject to limited review."); *see also Spear Pharm., Inc. v. William Blair & Co.*, 610 F. Supp. 2d 278, 280-81 (D. Del. 2009) (FDA delay in approving an ANDA due to petition did not break chain of causation); *Dr. Reddy's Labs, Ltd. v. aaiPharma, Inc.*, No. 01-cv-10102, 2002 WL 31059289, at *10-11 (S.D.N.Y. Sept. 13, 2002) (same).

Actavis argues that, even if it had not entered into a conspiracy with Takeda to perpetuate the 180-day exclusivity, the FDA would inevitably have approved its ANDA no earlier than October 2012. But this makes no sense. If Actavis had not entered the March 2010 pact, there would be no amendment, let alone a late one. And if Actavis were trying to gain market entry earlier but had to file some amendment to do so, a reasonable company in its shoes would make that filing earlier. And even if it were late, the tussle would have arisen all that much sooner, and reached the same quick (two month) resolution.

Finally, at the pleading stage, purchasers are not required to disprove all possible alternative causes where, as here, they have plausibly alleged that Actavis's conduct is a proximate cause of the harm they have suffered.

7. Teva's lack of first-to-file status does not warrant dismissing Teva.

Teva argues for dismissal because it was not a "first filer" for either ACTOS or ACTO*plus* met, and the exclusivity provisions of the Hatch-Waxman Act precluded it from entering the market for either drug until 180 days after one or more first filers entered the market.[312] This is wrong on the facts and the law.

Absent the false patent information submitted by Takeda, the FDA would not have required paragraph IV certifications to the '584 and '404 patents. There would have been no 180-day exclusivity, no need for first-to-file status, and no barrier to Teva's entry. Teva itself represented to a court its intent and ability, absent that roadblock, to gain market entry at the end of January 2011.[313] The "first filer" status created by the wrongful conduct cannot itself constitute an intervening cause resulting in dismissal of the case.

[312] Teva Br. 13-16.

[313] Compl. ¶ 283.

Teva might be arguing that – given Takeda's false information and the March 2010 pact entered into by the others – there was nothing it could do to get earlier market entry. But that too is not true; it had filed its counterclaim to have the Orange Book information corrected, and could have sought earlier market entry.[314] Nor are we required to project the result of that lawsuit; Teva chose instead to flip-flop, join the conspiracy to enjoy the fruits of the unlawful 180-day exclusivity, and delay its entry.[315] It is responsible for the delay with all the co-conspirators.

D. Bad faith is not an element of Sherman Act §§ 1 and 2 claims, but is pled here anyway.

Takeda argues that the false patent information claims must be dismissed because the complaint does not allege Takeda acted in bad faith. But bad faith is not required by the Sherman Act.[316] "[G]ood motives will not validate an otherwise anticompetitive practice."[317] Lack of allegations of bad faith is immaterial to false patent information claims.

Ignoring this uncontroversial antitrust principle, Takeda cites *Kroger Co. v. Sanofi-Aventis*,[318] which it claims held "antitrust claims alleging false Orange Book listings cannot be maintained without allegations of bad faith."[319] But this mischaracterizes *Kroeger*; in that case, the brand company's Orange Book listing was alleged to be wrongful *because* the patent was

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[314] Compl. ¶¶ 20, 236-37, 282-85.

[315] Compl. ¶¶ 289-94.

[316] *See Remeron*, 335 F. Supp. 2d at 532 ("*In considering whether the monopolist's conduct on balance is exclusionary for the purposes of Section 2, our focus is upon the effect of that conduct, not upon the intent behind it.*" (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001))).

[317] *NCAA v. Bd. of Regents*, 468 U.S. 85, 101 n.23 (1984); *see also Bd. of Trade of Chi. v. United States*, 246 U.S. 231, 238 (1918) ("[G]ood intention" cannot "save an otherwise objectionable" restraint of trade.); *Clorox Co. v. Sterling Winthrop, Inc.*, 117 F.3d 50, 60 (2d Cir. 1997) ("[I]t is settled that a good intention will not relieve a party from civil antitrust liability."); *Neurontin*, 2009 WL 2751029, at *8.

[318] 701 F. Supp. 2d 938 (S.D. Ohio 2010).

[319] Takeda Br. 18.

obtained by fraud – the wrongfulness of the Orange Book listing *depended* on a finding of *Walker Process* fraud.[320]

To the extent intent is germane, it is part of the defendants' affirmative defenses.[321] In other words, "[a] plaintiff is not required to plead the absence of such a defense,"[322] so the plaintiffs here need not have *any* allegations of bad faith.

And the facts here show Takeda acted deliberately and in bad faith. Takeda's false submissions were palpably incorrect.[323] They were an example of the kind of abusive Orange Book filings that gave rise to the 2003 amendments.[324] Takeda repeated the falsehood, insisting that the FDA act on them to impose upon generic applicants a duty to file paragraph IV certifications for patents that should not have been required.[325] It did so to delay generic entry – a fact that one of its later co-conspirators, Teva, concedes.[326]

In *Buspirone*, Judge Koeltl found allegations nearly identical to those here "sufficient" to establish bad faith.[327] There, as here, the plaintiffs alleged the defendants listed a patent in the Orange Book, knowing that the patent did not cover the relevant drug.[328] So, even if this Court were to impose a burden to plead bad faith, the direct purchaser class plaintiffs have done so.

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[320] *Kroger*, 701 F. Supp. 2d at 964.

[321] *Clorox*, 117 F.3d at 61; *see Geneva Pharms. Tech. Co. v. Barr Labs. Inc.*, 386 F.3d 485, 509 (2d Cir. 2004) ("The burden . . . shifts to the defendants to offer pro-competitive justifications for the arrangement.").

[322] *Chen v. Major League Baseball Props., Inc.*, 798 F.3d 72, 81 (2d Cir. 2015).

[323] Compl. ¶¶ 169-70, 175-76.

[324] Compl. ¶¶ 121-25.

[325] Compl. ¶ 232; *see* Ex. 9 to Lawton Decl., ECF No. 66-4.

[326] Compl. ¶ 237 (quoting Mem. Supp. Teva's Mot. Add Counterclaim 5-7).

[327] 185 F. Supp. 2d at 376-77. Judge Koeltl considered whether the plaintiffs had alleged bad faith because the brand company was seeking "qualified patent immunity," and that qualified immunity may be lost if the patentee acts in bad faith." *Id.* (citation omitted). Judge Koeltl did *not* discuss bad faith (or the lack thereof) in considering the sufficiency of the plaintiffs' substantive allegations or the defendants' pleas for *Noerr Pennington*'s limited immunity.

[328] *Id.* at 376.

E. The defendants' "early entry" and "license" labels are not a basis for dismissal.

The defendants argue that the agreements are immune from antitrust scrutiny because they provide "early-entry licenses."[329] This label affords them no solace.

The Supreme Court explicitly rejected the notion that the existence of an unexpired patent immunizes a patent settlement from antitrust attack.[330] In doing so, the court explained that looking only at "what the holder of a valid patent could do" *cannot* "answer the antitrust question," because by settling the parties avoid a determination of the *actual* scope of the patent.[331] And here, the inducement charges on the use claims of the '584 and '404 did not entitle Takeda to bar market entry for generic ACTOS products; it could only bar inducing conduct.

Nor are patent "licenses" immune from antitrust scrutiny. The Supreme Court has consistently sought "to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition."[332] Using licenses to achieve anticompetitive ends carries no immunity because Supreme Court precedents "make clear that patent-related settlement agreements can sometimes violate the antitrust laws";[333] "both within the settlement context and without, the Court has struck down overly restrictive patent licensing agreements – irrespective of whether those agreements produced supra-patent-permitted revenues."[334] Every post-*Actavis* case rejects the defendants' patent-license-immunity argument, including the Third Circuit's

[329] Joint Br. 10-12.

[330] *Actavis*, 133 S. Ct. at 2231.

[331] *Id.* at 2230-31.

[332] *Id.* at 2232-33.

[333] *Id.* at 2225.

[334] *Id.* at 2232.

decision addressing Lamictal.[335] "Patents give no protection from the prohibitions of the Sherman Act . . . when the licenses are used, as here, in the scheme to restrain."[336]

F. The purchasers should be granted leave to amend.

In the event this Court rules there are any material inadequacies regarding the allegations, leave to amend should be given. Leave to amend a complaint should be freely given, particularly in the absence of undue delay, bad faith, dilatory motive, repeated prior amendments, or undue prejudice to the defendants.[337]

The first direct purchaser action was commenced in April 2015.[338] At the defendants' request, the deadline for responding was stayed pending a decision on the complaint in the end-payor action.[339] Following that decision, and before any response was filed by the defendants, the purchasers sought leave to file an amended complaint.[340] That amended complaint – the first substantively amended complaint – is the one being challenged here. Its allegations are materially different from those contained in the end-payor complaint.[341]

If this Court finds the current allegations insufficient, there is no basis to deny the direct

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[335] See *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 406-08 (3d Cir. 2015); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015); *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1070 (N.D. Cal. 2014); *Nexium II*, 42 F. Supp. 3d at 264 (""[p]atents give no protection from the prohibitions of the Sherman Act . . . when the licenses are used . . . in [a] scheme to restrain."); *In re Niaspan Antitrust Litigation*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014).

[336] *United States v. New Wrinkle*, 342 U.S. 371, 378 (1952).

[337] *Foman v. Davis*, 371 U.S. 178, 182 (1962) (outright refusal to grant leave without any justifying reason appearing for the denial is not an exercise of discretion; but an abuse of that discretion); *see also Wight v. BankAmerica Corp.*, 219 F.3d 79, 91 (2d Cir. 2000); Fed. R. Civ. P. 15.

[338] Class Action Compl. & Jury Demand, Apr. 27, 2015, ECF No. 1. Following consolidation with another direct purchaser action, a consolidated complaint was filed. *See* Consol. Class Action Compl. & Jury Demand, June 4, 2015, ECF No. 14.

[339] Order, June 4, 2015, ECF No. 37.

[340] Mem. Supp. Mot. Leave File Amended Compl., Nov. 16, 2015, ECF No. 50.

[341] *See, e.g., id.* at 3 (listing major differences).

purchasers a chance to amend.[342] The defendants did not provide the settlement agreements – documents they now maintain are vital to the Court's assessment of its conduct – until *after* the operative complaint was filed. If the defendants intended to limit the direct purchasers to a single bite at the apple,[343] they should not have withheld these documents.

V. CONCLUSION

The motions should be denied and the parties should proceed with discovery.

Dated: March 21, 2016

Respectfully submitted,

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[342] *Williams v. Citigroup Inc.*, 659 F.3d 208, 213 (2d Cir. 2011); *see also Camoia v.City of New York*, No. 09-cv-2545, 2013 WL 867199, at *2 (E.D.N.Y. Mar. 7, 2013) ("Given that the parties are still at the pleadings stage, defendants are not prejudiced by permitting plaintiff to file a third amended complaint.").

[343] *See, e.g.*, Joint Br. 29 (citing no Rule 15 case law); Takeda Br. 19 (citing only this Court's opinion in the end-payor case noting that, in light of *three* prior amendments, the end-payor class plaintiffs would not be granted further leave to amend).

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: March 21, 2016

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