The Honorable Ken Schubert
Hearing Date: November 10, 2022 at 3:00 p.m.
With Oral Argument

STATE OF WASHINGTON
KING COUNTY SUPERIOR COURT

STATE OF WASHINGTON, Plaintiff, v. ALBERTSONS COMPANIES, INC.; ALBERTSON S COMPANIES SPECIALTY CARE, LLC; ALBERTSON'S LLC; ALBERTSON'S STORES SUB LLC; THE KROGER CO.; KETTLE MERGER SUB, INC., Defendants.	NO. 22-2-18046-3 SEA STATE OF WASHINGTON'S REPLY IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION

I. INTRODUCTION

This case is about protecting competition in one of the most critical markets for consumers in Washington: the neighborhood supermarket. Albertsons and Kroger have agreed to merge and, as a part of that agreement, Albertsons will issue a $4 billion dividend to its stockholders. This dividend is the first step in the well-worn playbook for supermarket mergers: it will cripple Albertsons and allow it to spin off weakened stores only to reacquire them once its merger is complete. The $4 billion dividend presents a blatant harm to competition and a clear violation of the Washington Consumer Protection Act. The State brought its motion for a

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preliminary injunction to enjoin the dividend because it constitutes (1) an unreasonable restraint of trade in violation of RCW 19.86.030; and (2) an unfair method of competition in violation of RCW 19.86.020.

Defendants claim they did not agree that Albertsons would pay the $4 billion dividend, but their press releases and public filings contradict them. Even if the Court finds there was no agreement, the State still succeeds on its unfair methods of competition claim. Defendants cannot show that issuance of a dividend that is 57 times more than usual, drains 75% of available cash, and saddles the company with an additional $1.5 billion in debt is a legitimate business concern that outweighs the public interest in competitive grocery markets.

Albertsons' securities filings and market reports support the State's concern that Albertsons has limited liquidity, and undermine assertions that Albertsons has enough cash. However, additional discovery would allow the State to provide more targeted expert analysis. At a preliminary injunction hearing, the Court does not reach the merits, and the plaintiff need only show likelihood of success on the merits. Review of the merger agreement and related public documents show that Commissioner Judson's decision to enter the Temporary Restraining Order was well-founded and that the Court should now enter a preliminary injunction.

II. ARGUMENT

A. Public Documents Confirm Defendants' Agreement, but the State Succeeds Even Without an Agreement.

Defendants' claim that they did not agree to pay the $4 billion dividend is not credible. It strains credulity to argue that the merger and dividend were not related when Defendants *jointly* announced the dividend "as part of the transaction" the day after they signed the merger agreement. Defendants' *joint* press release states, "As part of the transaction, Albertsons Cos. will pay a special cash dividend of up to $4 billion to its shareholders." Hanson Ex. C (WA000233). The same day, in Albertsons' 8-K, Albertsons' Executive Vice President,

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General Counsel and Secretary represented that she signed it on behalf of Albertsons pursuant to the requirements of the Securities Exchange Act of 1934. *Id.* Ex. C (WA000214). Item 8.01 of this 8-K incorporates the October 14th joint press release by reference. *Id.* Ex. C (WA000213).

Importantly, the State's unfair methods of competition claim succeeds even if there was no agreement. "[A] violation of RCW 19.86.020 does not require a finding of conspiracy." *State v. Black*, 100 Wn.2d 793, 800 (1984). Instead, "unilateral conduct which is unfair and anticompetitive may constitute a violation of RCW 19.86.020." *Id.* Defendants largely ignore this claim. Kroger says Albertsons' unilateral decision to pay the dividend does not violate RCW 19.86.020 because it is "motivated by legitimate business concerns." Dkt. 83 at 21 (quoting *Black*, 100 Wn.2d at 803); *see also* Dkt. 84 at 20. These assertions assume that (1) their business practices are legitimate and reasonable and (2) the practices do not injure the public. But the State demonstrated that this dividend is likely not a legitimate or reasonable business practice. The $4 billion dividend is 57 times more than Albertsons' last dividend and will leave Albertsons strapped for cash. Hanson Ex. V (WA000508). Albertsons' October 18th 10-Q shows that the dividend drains about 75% of available cash. Hanson Ex. D (WA000245). It also saddles Albertsons with an additional $1.5 billion in debt. Dkt. 72 at 9. In contrast, Albertsons' President and CFO Sharon McCollam concedes that Albertsons will only have $500 million in cash for existing operations. Dkt. 41 at 13. Operating on a shoestring cash flow is not a reasonable business practice. And the State demonstrated that the dividend will harm its statutory right and constitutional mandate to conduct an antitrust investigation of the merger, as well as harm Washington supermarket consumers, employees, and neighborhoods. "[O]ur Legislature recognized that a court must weigh the public interest in prohibiting anticompetitive conduct against the recognition that businesses need some latitude within which to conduct their trade." *Black*, 100 Wn.2d at 803. Here, the public interest in prohibiting anticompetitive conduct in the supermarkets outweighs Defendants' claimed "legitimate business concerns."

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While Defendants claim the injunction exposes Albertsons to shareholder liability in Delaware, Dkt. 83 at 1-2; Dkt. 84 at 4, this Court need not speculate about that because the focus of the Court's inquiry is on harm to the party seeking the injunction. *See, e.g.*, RCW 7.40.020 (discussing grounds for issuance of an injunction involving "injury to the plaintiff"). Besides, such litigation is unlikely to succeed because an illegal agreement is likely void under Delaware law. *See PHL Variable Ins. Co. v. Price Dawe 2006 Ins. Tr., ex rel. Christiana Bank & Tr. Co.*, 28 A.3d 1059, 1067 (Del. 2011) ("[C]ontracts that offend public policy or harm the public are deemed *void*[.]").

B. Public Documents Support the State's Economist's Declaration, but Additional Discovery Would Alleviate Any Concerns That He Has Not Fully Reviewed Albertsons' Financial Condition.

Public documents validate the State's concerns about Albertsons' cash flow and line of credit, and do not support Defendants' arguments. McCollum indicates that Albertsons has a $2.5 billion line of credit available through its asset-based lending facility. Dkt. 41 at 13. However, this is already $1.26 billion less than the amount of credit referenced in Albertsons' most recent 10-Q, which was $3.76 billion. Hanson Ex. V (WA000509). This raises questions whether Albertsons' asset-based lending facility will remain a viable line of credit. And McCollam's declaration further indicates that Albertsons has $500 million cash on hand. Dkt. 41 (13). However, this is already $400 million less than referenced in Albertsons' October 18th 10-Q. Dkt. 72 (9). This change reinforces Professor Weisbach's opinion questioning whether Albertsons will have an adequate line of credit and cash on hand after the dividend. Weisbach Supp. Decl. at 2.

Albertsons once again contradicts its own financial filings—signed and certified by McCollam—when it discusses cash flows. The 10-Q states the financial statements in the report "fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report." Ex. A (WA000137). It also

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states, "There can be no assurance, however, that our business will continue to generate cash flow at or above current levels or that we will maintain our ability to borrow under our ABL facility." Hanson Ex. V (WA000509). But now McCollam characterizes this statement as a "disclaimer . . . prudent for securities law purposes, but it does not mean that we perceive (or should perceive) a significant risk that our cash flows will decline so dramatically that we would not be able to continue to fund our three-year plan." Dkt. 41 at 19-20. So her signature and certification are inconsistent with her declaration. The Court should not allow Defendants to disavow statements made in certified filings merely because those statements are detrimental to their current positions in this litigation.

Defendants attempt to create a catch-22 by complaining that the State's expert only speaks to general economic principles, *see* Dkt. 84 at 23, while also refusing to produce documents and leave time for further discovery. The State issued civil investigative demands to both parties, but Defendants refused to produce responsive documents without confidentiality assurances beyond those provided in RCW 19.86.110. Dkt. 71 at 11 n.7. Once Professor Weisbach has received those documents, he will promptly produce additional analysis with reference to Defendants' specific financial situations, alleviating any concerns that the State's economic analysis is insufficiently focused on Albertsons. Weisbach Suppl. Decl. at 1. Under such circumstances, failure to grant a preliminary injunction is reversible error. *Nw. Gas Ass'n v. Washington Utilities & Transp. Comm'n*, 141 Wn. App. 98, 114–15 (2007) (court erred by transforming the preliminary injunction hearing into a permanent injunction trial without giving parties a full opportunity to present evidence at a trial on the merits).

C. The State Need Not Discuss Relevant Markets, and a Preliminary Injunction Hearing Does not Reach the Merits.

Finally, contrary to Kroger's arguments, the State need not engage in full rule of reason or quick look antitrust analysis at this stage of litigation. Dkt. 83 at 3, 17. Courts have found that unambiguous evidence of the terms of an agreement between competitors is direct evidence of a

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conspiracy. *See, e.g.*, *In re WellbutrinXL Antitrust Litig.*, 133 F. Supp. 3d 734, 770 (E.D. PA. 2015). Moreover, the Supreme Court emphasized that "whether the ultimate finding is the product of a presumption or actual market analysis, the essential inquiry remains the same—whether or not the challenged restraint enhances competition." *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 779–80 (1999). The context of the issuance of the dividend and the merger announcement, including public and internal documents, suffice for the Court to draw an inference of an anticompetitive agreement. But even if the Court were to find the State must use the rule of reason, "[a]t a preliminary injunction hearing, the plaintiff need not prove and the trial court does not reach or resolve the merits of the issues underlying [the] three requirements for injunctive relief." *Nw. Gas Ass'n*, 141 Wn. App. at 116. Instead, "the trial court considers only the *likelihood* that the plaintiff will ultimately prevail at a trial on the merits." *Id.* The State has more than made that showing in the limited time since Defendants announced the dividend and with limited available documents.

III. CONCLUSION

Significant harm will come to Washington consumers, employees, and neighborhoods if the Court allows Albertsons to drain its cash before antitrust enforcers have a chance to evaluate the merger. Granting the preliminary injunction preserves the status quo, and encourages Defendants to work cooperatively with enforcers to facilitate required merger review—including the $4 billion dividend that Defendants agreed Albertsons would pay its shareholders as part of the transaction.

DATED this 10th day of November 2022.

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I certify that this memorandum contains 1,731 words, in compliance with the Local Civil Rules.

DECLARATION OF SERVICE

I declare that I caused the foregoing document to be electronically served through the Court's Electronic Filing System on all counsel of record in this action.

DATED this 10th day of November 2022 in Seattle, Washington.

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STATE OF WASHINGTON, Plaintiff, v. ALBERTSONS COMPANIES, INC.; ALBERTSON S COMPANIES SPECIALTY CARE, LLC; ALBERTSON'S LLC; ALBERTSON'S STORES SUB LLC; THE KROGER CO.; KETTLE MERGER SUB, INC., Defendants.	NO. 22-2-18046-3 SEA NOTICE OF NON-WASHINGTON AUTHORITIES TO STATE OF WASHINGTON'S REPLY IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Local Civil Rule 7(b)(5)(B)(v), Plaintiff State of Washington provides copies of the non-Washington authorities cited in its Reply in Support of Its Motion for Preliminary Injunction:

1. *PHL Variable Ins. Co. v. Price Dawe 2006 Ins. Tr., ex rel. Christiana Bank & Tr. Co.*, 28 A.3d 1059 (Del. 2011)

2. *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734 (E.D. Pa. 2015)

3. *Cal. Dental Ass'n v. FTC*, 526 U.S. 756 (1999)

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DECLARATION OF SERVICE

I declare that I caused the foregoing document to be electronically served through the Court's Electronic Filing System on all counsel of record in this action.

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28 A.3d 1059
Supreme Court of Delaware.

PHL VARIABLE INSURANCE COMPANY, Plaintiff Appellant,
v.
PRICE DAWE 2006 INSURANCE TRUST, by and through its trustee, CHRISTIANA BANK AND TRUST COMPANY, et al., Defendant Appellees.

No. 174, 2011.
|
Submitted: Aug. 17, 2011.
|
Decided: Sept. 20, 2011.

Synopsis

Background: Insurer sought a judicial declaration that a life insurance policy that lacked an insurable interest was void as an illegal contract wagering on human life. Owner of policy filed motion to dismiss for failure to state a claim. The United States District Court for the District of Delaware denied the motion and certified questions of law.

Holdings: The Supreme Court, Steele, C.J., held that:

a life insurance policy lacking an insurable interest is void as against public policy and, thus, never comes into force, making the statutorily required incontestability provision of the policy inapplicable;

the statutory insurable interest requirement is not violated where the insured procures a life insurance policy with the intent to immediately transfer the benefit to an individual or entity lacking an insurable interest, so long as the insured procured or effected the policy and the policy is not a mere cover for a wager;

if a third party financially induces the insured to procure a life insurance contract with the intent to immediately transfer the policy to a third party, the contract lacks an insurable interest;

an insured cannot procure or effect a policy, within meaning of statute providing that the insured is free to procure or effect a policy on his own life for the benefit of anyone, without actually paying the premiums; and

the insurable interest statute confers upon a trustee an insurable interest in the life of the individual insured who established the trust when the insured intends to transfer the beneficial interest in the trust to a third-party investor with no insurable interest, as long as the individual insured actually established the trust, and the life insurance is procured for a legal purpose and not as a cover for an illegal wager contract.

Questions answered.

Procedural Posture(s): Motion to Dismiss; Motion to Dismiss for Failure to State a Claim.

***1062** Certification of Questions of Law from the United States District Court for the District of Delaware, C.A. No. 10–964.

Questions Answered: Question One **AFFIRMATIVE;** Question Two **NEGATIVE** and, Question Three **AFFIRMATIVE.**

Attorneys and Law Firms

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Opinion

STEELE, Chief Justice:

This is a proceeding, under Article IV, Section 11(8) of the Delaware Constitution and Supreme Court Rule 41, on a question of law certified to, and accepted by us, from the United States District Court for the District of Delaware. The certified questions arise from two similar cases—*PHL Variable Insurance Co. v. Price Dawe 2006 Insurance Trust* (Dawe) and *Lincoln National Life Insurance Co. v. Joseph*

Schlanger 2006 Insurance Trust (*Schlanger*). [1] In both cases, an insurer sought a judicial declaration that a life insurance policy that lacked an insurable interest was void as an illegal contract wagering on human life. The district court denied both motions to dismiss and certified three questions to the Supreme Court of Delaware concerning the incontestability provision required under 18 *Del. C.* § 2908 and the insurable interest requirement under 18 *Del. C.* § 2704.

FACTUAL AND PROCEDURAL BACKGROUND

The Price Dawe 2006 Insurance Trust is a Delaware statutory trust that Price Dawe formed in December 2006 with a family trust as the beneficiary. Dawe was the beneficiary of the family trust. PHL Variable Insurance Co. (Phoenix) issued a $9 million Delaware life insurance policy on Dawe's life with an issue date of March 8, 2007. The Dawe Trust was the owner and beneficiary of the policy. The policy contains an incontestability provision stating that "[t]his policy shall be Incontestable after it has been in force for two years from the Issue Date, except for fraud, or any provision for reinstatement or policy change requiring evidence of insurability." Dawe died on March 3, 2010. On June 9, 2010, the Dawe Trust made a claim to Phoenix for the death benefit. Phoenix first contested the policy by filing this lawsuit on November 10, 2010, approximately 3 ½ years after the policy issue date. These facts are undisputed and constitute the official record for our purposes. [2]

In its original complaint, Phoenix contended that Dawe did not qualify, and had no legitimate need, for a $9 million life insurance policy. The insurance company claims Dawe misrepresented his income and assets in his application and that he was financially induced into participating in the transaction as part of a stranger originated life insurance ("STOLI") scheme. Phoenix further alleges that Dawe never intended to retain the policy, and always intended that the policy would ***1064** be immediately transferred to an unrelated third party investor, GIII, a private investing entity. Phoenix claims that the defendant Trust and Dawe were used as straw men to allow GIII, which had no insurable interest, to conceal a wager on Dawe's life. Phoenix more specifically contends that on or about May 14, 2007, less than two months after the policy went into force, GIII formally purchased the beneficial interest of the Dawe Trust from the Family Trust for $376,111, and did not file a change of ownership or change of beneficiary form with the company. After Dawe died, Phoenix received two competing claims for the death benefit, leading to an investigation that allegedly revealed the true nature of Dawe's life insurance transaction. Phoenix then filed suit in the United States District Court for the District of Delaware in order to obtain a declaration that the policy is void. After denying the defendant Trust's motion to dismiss, the district court certified three questions of Delaware law to this Court, which we accepted.

THE CERTIFIED QUESTIONS

The questions presented are issues of law which this Court decides *de novo.* [3]

1) Does Delaware law permit an insurer to challenge the validity of a life insurance policy based on a lack of insurable interest after the expiration of the two-year contestability period required by 18 *Del.* C. § 2908? [4]

2) Does 18 *Del. C.* § 2704(a) and (c)(5) prohibit an insured from procuring or effecting a policy on his or her own life and immediately transferring the policy, or a beneficial interest in a trust that owns and is the beneficiary of the policy, to a person without an insurable interest in the insured's life, if the insured did not ever intend to provide insurance protection for a person with an insurable interest in his or her life?

3) Does 18 *Del. C.* § 2704(a) and (c)(5) confer upon the trustee of a Delaware trust established by an individual insured an insurable interest in the life of that individual when, at the time of the application for life insurance, the insured intends that the beneficial interest in the Delaware trust would be transferred to a third-party investor with no insurable interest in that individual's life following the issuance of the life insurance policy?

ANALYSIS

I. CERTIFIED QUESTION ONE: CONTESTABILITY

The first certified question, shared by both *Dawe* and *Schlanger,* concerns whether an insurer may claim that a life insurance policy never came into existence, on the basis of a lack of insurable interest, where the challenge occurs after the insurance contract's mandatory contestability period expires. As certified by the district court in *Dawe:*

> Does Delaware law permit an insurer to challenge the validity of a life insurance policy based on a lack of insurable interest after the expiration of the two-year ***1065** contestability period required by 18 *Del. C.* § 2908? [5]

Our answer to question one is "**YES.**" That answer is consistent with that reached by the majority of courts; namely, that a life insurance policy lacking an insurable interest is void as against public policy and thus never comes into force, making the incontestability provision inapplicable.

Phoenix and *amicus curiae* American Council of Life Insurers argue that we should side with the majority of courts and hold that the expiration of a contractual contestability period mandated by the Delaware Insurance Code does not bar an insurer from contesting the validity of a life insurance policy based on a lack of insurable interest. They contend that under Delaware law, a life insurance policy without an insurable interest is nothing more than a wager on human life that is void as against public policy. As a result, the insurers assert, the incontestability provision does not bar their suits because the provision, which is only one component of the entire life insurance contract, never legally came into effect at all.

The defendant Dawe Trusts argue that we should side with the courts of New York and Michigan and hold that plaintiffs' suits are barred by the incontestability provision of each life insurance contract. They contend that the plain meaning of the pertinent provisions of the Insurance Code makes clear that these provisions bar all types of challenges to a life insurance policy's validity after the required contestability period expires. The defendants argue that the distinction between contracts void at the outset and those voidable at the option of the innocent party is irrelevant, and that life insurance policies in violation of Delaware's insurable interest requirement are not automatically void.

A. *Historical Background*

An incontestability clause is a contractual provision wherein the insurer agrees that, after a policy has been in force for a given period of time, that it will not contest the policy based on misrepresentations in the insurance application. [6] The insurance industry has used incontestability clauses for more than 100 years to encourage customers to purchase insurance. [7] Originating in England in the mid-nineteenth century, incontestability clauses were created as a marketing device to increase public trust in insurance companies. [8] Before incontestability clauses were introduced, insureds sometimes paid premiums for a long period of time only to have the insurer declare the contract void because of misrepresentations in the application. [9] These misrepresentations were often innocent, but by that point the insured was deceased and unable to address the basis of the challenge. [10] Insurance companies therefore created the incontestability ***1066** clause in order to address consumer uncertainty.

Incontestability clauses provide security in financial planning for the insured, while also providing an insurer a reasonable opportunity to investigate any misrepresentations in the application. These provisions essentially serve the same function as statutes of limitation and repose. [11] By the early twentieth century, life insurance policies included incontestability clauses as a matter of industry practice. [12] Forty three states have adopted mandatory contestable clauses relating to life insurance policies, while four states also have incontestability clauses relating to other types of insurance. [13] Consequently, over the years, the clause has become a standard provision in most, if not all, life insurance contracts. [14]

B. *Delaware Insurance Code*

The Delaware Insurance Code requires that all life insurance policies include a incontestability clause. [15] The applicable statute in relevant part provides:

> There shall be a provision that the policy shall be incontestable after it has been *in force* during the lifetime of the insured for a period of not more than 2 years after its date of issue, except for (1) nonpayment of premiums, and (2) at the insurer's option, provisions relating to benefits in the event of total and permanent disability and provisions granting additional benefits specifically against death by accident or accidental means. [16]

Section 2917 of the Insurance Code affirms the class of challenges that are covered by a mandatory incontestability

provision, but also lists certain challenges that are not precluded by this language:

> A clause in any policy of life insurance providing that such policy shall be incontestable after a specified period shall preclude only a contest of the *validity of the policy* and shall not preclude the assertion at any time of defenses based upon provisions in the policy which exclude or restrict coverage, whether or not such restrictions or exclusions are excepted in such clause. [17]

The defendant trusts argue that the plain language of section 2917 makes clear that an incontestability clause precludes any challenge to the enforceability of a life insurance contract after the two-year contestability period expires. This argument ignores the fact that the Delaware General Assembly chose to implement its goals through a mandatory *contractual* term, as distinguished from a direct ban on challenges to policy validity after a certain time. This creates an ambiguity in section 2917 on the meaning of the word "validity." We read the statute to be entirely subject to Delaware's existing law of contract formation. Put simply, under the Delaware statute, the incontestability provision should be treated like any other contract term. That reading is supported by the plain language of section 2908, which states that "[t]here shall be a provision that the policy shall be incontestable after it has been *in force* during the lifetime of the ***1067** insured for a period of not more than 2 years." These words accordingly make the incontestability period *directly contingent* on the formation of a valid contract. That is the view of the majority of state courts that have considered this question. [18]

C. *Distinguishing between void and voidable contracts*

As with all contracts, fraud in the inducement renders a life insurance policy voidable at the election of the innocent party. [19] Certain agreements, however, are so egregiously flawed that they are void at the outset. These arrangements are often referred to as void *ab initio,* Latin for "from the beginning." A court may never enforce agreements void *ab initio,* no matter what the intentions of the parties. The United States District Court for the District of Delaware succinctly explained this basic contract doctrine in the context of fraud:

> Under the common law of contracts, there is a distinction between fraud in the inducement and fraud in the "factum," or execution. Fraud in the factum occurs when a party makes a misrepresentation that is regarded as going to the very character of the proposed contract itself, as when one party induces the other to sign a document by falsely stating that it has no legal effect. If the misrepresentation is of this type, then there is no contract at all, or what is sometimes anomalously described as a void, as opposed to voidable, contract. If the fraud relates to the inducement to enter the contract, then the agreement is "voidable" at the option of the innocent party. The distinction is that if there is fraud in the inducement, the contract is enforceable against at least one party, while fraud in the factum means that at no time was there a contractual obligation between the parties. [20]

Under Delaware common law, contracts that offend public policy or harm the public are deemed *void* as opposed to voidable. [21]

D. *A life insurance contract that lacks an insurable interest at inception is void ab initio*

Under Delaware common law, if a life insurance policy lacks an insurable interest at inception, it is void *ab initio* [22] ***1068** because it violates Delaware's clear public policy against wagering. [23] It follows, therefore, that if no insurance policy ever legally came into effect, then neither did any of its provisions, including the statutorily required incontestability clause. "[T]he incontestable clause is no less a part of the contract than any other provision of it." [24] As a result, the incontestability provision does not bar an insurer from asserting a claim on the basis of a lack of insurable interest. [25] We reject the contrary result reached in *New England Mut. Life Ins. Co. v. Caruso,* because in that case the New York court, unlike Delaware and most other jurisdictions, held that a policy lacking an insurable interest was *not* void at the outset. [26]

Therefore, an insurer can challenge the enforceability of a life insurance contract after the incontestability period where a lack of insurable interest voids the contract. For this reason we answer Question one affirmatively.

II. CERTIFIED QUESTION TWO: INTENT TO TRANSFER

The second certified question concerns whether the statutory insurable interest requirement is violated where the insured procures a life insurance policy with the intent to immediately transfer the benefit to an individual or entity lacking an insurable interest:

> Does 18 *Del. C.* § 2704(a) and (c)(5) prohibit an insured from procuring or effecting a policy on his or her own life and immediately transferring the policy, or a beneficial interest in a trust that owns and is the beneficiary of the policy, to a person without an insurable interest in the insured's life, if the insured did not ever intend to provide insurance protection for a person with an insurable interest in his or her life?

Our answer to question number two is "**NO,**" so long as the insured procured or effected the policy and the policy is not a mere cover for a wager.

PHL and ACLI argue that the Dawe policy violates Delaware's insurable interest statute because Dawe procured the policy with the intent to transfer it immediately to an investor without an insurable interest. They argue that the insurable interest requirement is a substantive regulation that would be completely undermined by ignoring intent. The insurers assert that the opposite result is illogical because it would give a procedural loophole to STOLI scheme promoters.

***1069** The Dawe Trust counters that reading an intent requirement into the insurable interest statute is at odds with its plain language. The Trust accordingly urges this Court not to engraft an intent element onto the law because it would be at odds with our principles of statutory construction. More specifically, the Dawe Trust argues that insurable interest is determined only at the moment the life insurance contract becomes effective. According to the Dawe Trust, the Delaware Insurance Code abrogates older Delaware cases decided at common law, which looked beyond the initial beneficiary to the intent of the parties when determining insurable interest. The Trust also emphasizes that life insurance policies are freely assignable under Delaware law.

A. *Historical Background*

Since the initial creation of life insurance during the sixteenth century, speculators have sought to use insurance to wager on the lives of strangers.[27] In England, dead pools and the use of insurance to wager on strangers' lives actually became a popular pastime.[28] In response, Parliament enacted the Life Assurance Act of 1774 which prohibited the use of insurance as a wagering contract unlinked to a demonstrated economic risk.[29] Although the Act did not use the words "insurable interest," the concept was embedded in the Act. This principle eventually crossed the herring pond and became firmly rooted in the common law of every state in the Union.[30] More than a century ago, the United States Supreme Court concisely articulated the public policy behind the insurable interest requirement:

> [T]here must be a reasonable ground, founded upon the relations of the parties to each other, either pecuniary or of blood or affinity, to expect some benefit or advantage from the continuance of the life of the assured. Otherwise the contract is a mere wage, by which the party taking the policy is directly interested in the early death of the assured. *Such policies have a tendency to create a desire for the event.* They are, therefore, independently of any statute on the subject, condemned, as being against public policy.[31]

Over the last two decades, however, an active secondary market for life insurance, sometimes referred to as the life settlement industry, has emerged.[32] This secondary market allows policy holders who no longer need life insurance to receive necessary cash during their lifetimes. The market provides a favorable alternative to allowing a policy to lapse, or receiving only the cash surrender value. The secondary market for life insurance is perfectly legal. Indeed, today it is highly regulated. In fact, most states have enacted statutes governing secondary market transactions, ***1070** and all jurisdictions permit the transfer or sale of legitimately procured life insurance policies. Virtually all jurisdictions, nevertheless, still prohibit third parties from creating life insurance policies for the benefit of those who have no relationship to the insured. These policies, commonly known as "stranger originated life insurance," or STOLI, lack an insurable interest and are thus an illegal wager on human life.

In approximately 2004, securitization emerged in the life settlement industry. Under this investment method, policies are pooled into an entity whose shares are then securitized and sold to investors.[33] Securitization substantially increased the demand for life settlements, but did not affect the supply side, which remained constrained by a limited number of seniors who had unwanted policies of sufficiently high value. As a result, STOLI promoters sought to solve the supply problem by generating new, high value policies.

B. ***The Insurable Interest Statute is Ambiguous***

The plain language of 18 *Del. C.* § 2704(a) is ambiguous because a literal reading of the statute would permit wagering contracts, which are prohibited by the Delaware Constitution.[34] The rules of statutory construction are well settled.[35] First, we must decide if the statute is ambiguous.[36] A statute is ambiguous if it is susceptible of two reasonable interpretations[37] or if a literal reading of its terms "would lead to an unreasonable or absurd result not contemplated by the legislature."[38] If it is unambiguous, then there is no room for judicial interpretation and "the plain meaning of the statutory language controls."[39] If, on the other hand, the statute is ambiguous, then we consider it as a whole and we read each section in light of all the others to produce a harmonious whole.[40] Only when a statute is ambiguous do we look for guidance to its apparent purpose and place it as part of a broader statutory scheme.[41] We also ascribe a purpose to the General Assembly's use of particular statutory language and construe it against surplusage if reasonably possible.[42] Courts should, however, interpret statutory law consistently with pre-existing common law unless the legislature expresses a contrary intent.[43] We accordingly must approach section 2704(a) with these principles of statutory construction in mind.

The Delaware Constitution prohibits all forms of gambling unless it falls ***1071** within one of the enumerated exceptions.[44] Nearly one hundred years ago, the United States Supreme Court explained, "[a] contract of insurance upon a life in which the insured has no interest is a pure wager...."[45] Accordingly, a life insurance policy procured or effected without an insurable interest is a wager on the life of the insured the Delaware Constitution prohibits. Because a literal reading of the statute creates an absurd result not contemplated by the General Assembly, we must interpret the statute in conformity with both Delaware law and the General Assembly's intent.

C. ***The Delaware common law required an insurable interest***

Phoenix and ACLI argue that the statutory language prohibits entering into a life insurance contract with the intent immediately to transfer the policy to someone without an insurable interest. The United States District Court for the District of Delaware has reached the same conclusion.[46] ACLI correctly points out that under Delaware common law, an assignment may not be used as a formalistic cover for what in substance amounts to a wager.[47] Phoenix and ACLI also argue that ignoring intent would result in an illogical triumph of form over substance that would completely undermine the policy goals behind the insurable interest requirement.[48] We agree.

For nearly one hundred years, Delaware law has required an insurable interest as a way to distinguish between insurance and wagering contracts. In *Baltimore Life Ins. Co. v. Floyd,* the court explained:

> [T]he legitimate scheme of life insurance is inclined to be distorted and to some it affords an invitation for a mischievous kind of gambling. To avoid this misuse of a most useful character of undertaking, in which a beneficiary may become interested in the early death of the insured, it is held that the insurance upon a life shall be effected and resorted to only for some benefit incident to or contemplated by the insured, and that insurance procured upon a life by one *or in favor of one under circumstances of speculation or hazard* amounts to a wager contract and is therefore void, upon the theory that it contravenes public policy.

***1072** The presence of an insurable interest on the part of the beneficiary is urged as a request to avoid the appearance of a wager contract, holding that without such an interest, the interest in the beneficiary is speculative. An insurable interest of the beneficiary may be shown by proof of the fact of relationship between the beneficiary and the insured within certain degrees, and by proof of pecuniary interest, such as arise between partners and between debtors and creditors. Evidence of such an insurable interest is evidence that the contract is not a wager and is evidence of the contracts validity.

> If the beneficiary has an insurable interest *and the transaction is otherwise legal,* the policy is valid; if he has not such an interest the policy may be valid, if the transaction is bona fide and free from speculation. [49]

In *Floyd,* the court analyzed the intricacies of the insurable interest requirement in detail, including the general rule that, where "the transaction is bona fide, a person may take insurance upon his own life for the benefit of one having no insurable interest in his life." [50] This general rule is based upon "the theory that it is not reasonable to suppose that a person will insure his own life for the purpose of speculation." [51] However, the identity of the contracting party is not dispositive to the determination of whether an insurance policy is bona fide.

> One of the tests as to the validity of the contract is to determine by whom the premiums are to be paid. If the one taking the insurance pays the premiums, the transaction is generally upheld. But there is a strong, though not universal, tendency to condemn contracts in which the premiums are paid by the beneficiary [who holds no insurable interest]. [52]

In 1968, the General Assembly codified the insurable interest requirement, [53] in a statute which essentially restated the substantive considerations of *Floyd.* [54] When the General Assembly enacted section 2704 in 1968, it specified categories of persons who have an insurable interest in the life of the insured and who may "procure or cause to be procured" life insurance on the insured. These categories include anyone having a "lawful and substantial economic interest" in the insured's life, parties to a contract for the purchase or sale of a business interest, and any relatives having a "substantial interest engendered by love and affection." [55]

D. *The General Assembly codified the common law insurable interest requirement*

The tenets of statutory construction require us to interpret statutes consistent with the common law [56] unless the statutory language clearly and explicitly expresses ***1073** an intent to abrogate the common law. [57] Although the insurable interest requirement is originally a creature of both state and pre-*Erie* [58] federal common law, [59] it is now codified in the Delaware Insurance Code. In relevant part, the Insurance Code provides:

> Any individual of competent legal capacity may procure or effect an insurance contract upon his/her own life or body for the benefit of any person, but no person shall procure or cause to be procured any insurance contract upon the life or body of another individual unless the benefits under such contract are payable to the individual insured or his/her personal representatives or to a person having, at the time when such contract was made, an insurable interest in the individual insured. [60]

Section 2704(a) has two parts. The first clause provides that a person may procure or effect insurance on *his own life* for the benefit of anyone. This clause has no limiting language concerning intent, or even requires the beneficiary to have an insurable interest in the life of the insured. Section 2704(a) provides that "[a]ny individual of competent legal capacity may procure or effect an insurance contract upon his/her own life or body for the benefit of *any person* ..." [61] In contrast to the first clause, the remainder of the section concerns procuring insurance on the *life of another.* Under this language, policies "procure[d] or cause[d] to be procured" on the life of someone other than the person seeking the insurance must be payable to the "insured or his/her personal representatives or to a person having, *at the time when such contract was made,* an insurable interest in the individual insured." [62]

Although the statute has been periodically updated, [63] the substance of Delaware law on insurable interest has remained the same. An insured is permitted to take out an insurance policy on his own life, but the law prohibits persons other than the insured from procuring or causing to be procured insurance, unless the benefits are payable to one holding an insurable interest ***1074** in the insured's life. [64]

The insurable interest requirement serves the substantive goal of preventing speculation on human life. For this reason, section 2704(a) requires more than just technical compliance at the time of issuance. Indeed, the STOLI schemes are created to feign technical compliance with insurable interest statutes. If a third party procures life insurance on another person or causes the procurement of life insurance on another person—the beneficiary of that contract must have an insurable interest in the life of the insured. At issue is whether a third party having no insurable interest can use the insured as a means to procure a life insurance policy that the statute would otherwise prohibit. Our answer is no, because if that

third party uses the insured as an instrumentality to procure the policy, then the third party is actually causing the policy to be procured, which the second clause of section 2704(a) proscribes.

The statute defines the moment in time the insurable interest requirement applies—"the time when such contract was made," i.e., the moment the life insurance contract becomes effective. [65] Thus, the insurable interest requirement does not place any restrictions on the subsequent sale or transfer of a bona fide life insurance policy. Indeed, section 2720 of the Delaware Insurance Code makes life insurance policies assignable to anyone, even a stranger, *subject to any contractual restrictions in the policy.* [66] Section 2720 comports with the United States Supreme Court decision *Grigsby v. Russell* [67] and does not abrogate the common law as established in *Baltimore Life Ins. Co. v. Floyd.* Read this way, a life insurance policy that is validly issued is assignable to anyone, with or without an insurable interest, at any time. The key distinction is that a third party cannot use the insured as a means or instrumentality to procure a policy that, when issued, would otherwise lack an insurable interest.

Recently, the New York Court of Appeals answered a similar certified question, holding that an insured may procure insurance on his own life with the intent to immediately assign it to another. We find *Kramer v. Phoenix Life Ins. Co.* [68] distinguishable because the insured purchased policies on his own life and a provision of the New York insurance law [69] that did not contain an insurable interest requirement ***1075** governed those policies. Moreover, *Kramer* was decided on a narrow set of issues applying unique New York insurance statutes, which are not applicable here. [70] Notably, after *Kramer* the New York legislature revised the state's insurance laws to prohibit STOLI transactions, limiting the precedential value of *Kramer,* even in New York. [71]

E. *Determining who procured or effected the policy*

The General Assembly did provide one specific exception to the insurable interest requirement, which allows issuance of a policy where the person paying the premiums does not have an insurable interest in the insured's life. Under that exception, the beneficiary must be a benevolent, educational or religious institution and the payor be designated as the owner. [72] The logical implication of this exception is that in cases not covered, it would be impermissible if the person paying the premium had no insurable interest in the life of the insured or if the person paying the premiums were not the policy owner. For this reason, we must interpret section 2704 and section 2705 in harmony and not render the language of section 2705 superfluous.

"If the insured procures the policy at the behest of another, the policy may nevertheless lack a legally insurable interest." [73] To determine who procured the policy, we look at who pays the premiums. [74] Indeed, section 2704(a) and section 2705 read together require the insured to fund the premiums on the policy unless the payor is a charitable, benevolent, educational, or religious institution. Therefore, if a third party financially induces the insured to procure a life insurance contract with the intent to immediately transfer the policy to a third party, the contract lacks an insurable interest. Stated differently, if an insured procures a policy as a mere cover for a wager, then the insurable interest requirement is not satisfied. [75]

An insured's right to take out a policy with the intent to immediately transfer the policy is not unqualified. That right is limited to bona fide sales of that policy taken out in good faith. [76] A bona fide insurance policy sale or assignment requires that the insured take out the policy in good faith—not as a cover for a wagering contract. [77] Certainly, if A cannot ***1076** procure a life insurance policy on the life of B without having an insurable interest in B's life then A cannot induce B's procurement of a life insurance policy with the intent to allow A to immediately purchase the policy for a nominal sum. "If the first is a speculating and wagering policy so is the last." [78] Thus, section 2704 requires courts to scrutinize the circumstances under which the policy was issued and determine who in fact procured or effected the policy.

Payment of the premiums by the insured, as opposed to someone with no insurable interest in the insured's life, provides strong evidence that the transaction is bona fide. [79] Under section 2704(a), the insured is free to "procure or effect" a policy on his own life for the benefit of anyone. Life insurance policies, however, do not come into effect without premiums, so an insured cannot "procure or effect" a policy without actually paying the premiums. Notably, section 2708, which prohibits policies issued without the consent of the insured except in narrow situations not present here, utilizes the phrase "applies therefore or has consented thereto in writing." By implication, "procuring or effecting" a policy has to be something more than simply applying for a policy or providing written consent to the policy's issuance. Therefore,

if a third party funds the premium payments by providing the insured the financial means to purchase the policy then the insured does not procure or affect the policy. Accordingly, third parties are prohibited from procuring or causing to be procured insurance contracts on the life of the insured unless the policy benefits are payable to someone with an insurable interest.

In summary, the insured's subjective intent for procuring a life insurance policy is not the relevant inquiry. The relevant inquiry is who procured the policy and whether or not that person meets the insurable interest requirements.

III. CERTIFIED QUESTION THREE: THE TRUST'S INTEREST

The third certified question concerns whether the relevant statutory provisions confer upon a trustee an insurable interest in the life of the individual insured who established the trust if the insured intends to transfer the beneficial interest in the trust to a third-party investor with no insurable interest. As certified by the district court:

> Does 18 *Del.* C. § 2704(a) and (c)(5) confer upon the trustee of a Delaware trust established by an individual insured an insurable interest in the life of that individual when, at the time of the application for life insurance, the insured intends that the beneficial interest in the Delaware trust would be transferred to a third-party investor with no insurable interest in that individual's life following the issuance of the life insurance policy?

Our answer to question number three is "**YES,**" as long as the individual insured actually established the trust. If, however, the insured does not create and fund the trust then the relationship contemplated under section 2704(c)(5) is not satisfied.

Phoenix argues section 2704(c)(5) must be interpreted in the context of section 2704(a) and Delaware common law, which prohibit wagering contracts channeled through trusts. Dawe argues that section 2704(c)(5) recognizes a trust's right to own life insurance policies by conferring on a trustee a broad insurable interest in the life of the insured. Delaware statutory ***1077** trusts did not exist at common law. The policy of the Delaware Statutory Trust Act is to give maximum effect to freedom of contract and the enforceability of governing instruments, and its provisions are to be construed broadly even if in derogation of the common law.

A. *Recent Changes to Section 2704(c)(5)*

Section 2704(c) describes categories of persons and entities having an insurable interest in the life of the insured. Section 2704(c)(5) confers on the trustee of a trust an insurable interest in the life of the person who established the trust.

On July 13, 2011, after the parties completed briefing,[80] the Governor signed Senate Bill No. 83, an Act to amend Titles 10, 12, 18, and 25 of the Delaware Code relating to judicial procedure, fiduciary relations, insurance and property. Section 17 of that Act addresses 18 *Del. C.* § 2704(c)(5).

At the time that the parties briefed the certified questions, section 2704(c)(5) provided in relevant part that:

> The trustee of a trust established by an individual has an insurable interest in the life of that individual and the same insurable interest in the life of any other individual as does any person who is treated as the owner of such trust for federal income tax purposes.

Section 2704(c)(5) now provides, in pertinent part, that:

> The trustee of a trust *created and initially funded* by an individual has an insurable interest in the life of that individual and the same insurable interest in the life of any other individual as does any person who is treated as the owner of such trust for federal income tax purposes *without regard to:*
>
> *a. The identity of the trust beneficiaries*
>
> *b. Whether the identity of the trust beneficiaries changes from time to time; and*

c. The means by which any trust beneficiary acquires a beneficial interest in the trust. [81]

Importantly, the prior statutory language did not limit who may be a trust beneficiary or require the beneficiary to have an independent insurable interest. The revised language expressly states that a trustee has an insurable interest "without regard to the identity of the trust beneficiaries, whether the [trust beneficiaries] change ..., and the means by which any trust beneficiary acquires a beneficial interest in the trust." [82] The Synopsis of Senate Bill 83 states the revisions were intended to "clarify the provisions of current law" concerning when a trust has an insurable interest, meaning the recent changes did not alter the earlier statute. Thus, a trust has an insurable interest in the life of the person who established —*created and initially funded*—the trust without regard to whether the beneficial interest in the trust is subsequently sold or transferred.

B. *Section 2704(c)(5) must be read in harmony with Section 2704(a)*

As noted in Section IIC above, we must interpret section 2704(c) in light of ***1078** section 2704(a) to create harmony within the statute. Section 2704(c)(5) requires more than just technical compliance with section 2704(a), otherwise section 2704(c)(5) would expressly authorize wagering contracts, so long as it was conducted through a trust for whom the insured was the settlor or grantor. And as explained in Question two, a life insurance policy procured or effected without an insurable interest is a wager on the life of the insured and is prohibited by the Delaware Constitution.

Section 2704(c)(5) only grants the trustee of a Delaware trust an insurable interest in the life of the individual insured if the trust is "established" by the individual insured. The insured, as settlor or grantor, must both create and initially fund the trust corpus. This requirement is not satisfied if the trust is created through nominal funding as a mere formality. If the funding is provided by a third party as part of a pre-negotiated agreement—then the substantive requirements of sections 2704(a) and 2704(c)(5) are not met.

Parties cannot use section 2704(c)(5) to do indirectly what 2704(a) clearly prohibits parties from doing directly. The general rule, as explained in Question two, "is that all persons have an insurable interest in their own life ... and may ... insure their life in good faith for the benefit of any person whom they see fit to name as the beneficiary, regardless of whether such person has an insurable interest in their life, provided it not be done by way of cover for a wagering policy." [83] Thus, an individual insured can procure a policy and name his own trust as the owner and beneficiary of that validly procured life insurance policy, and the policy complies with the first clause of section 2704(a). Additionally, the individual insured can establish—create and initially fund—a trust for the purpose of procuring life insurance on the individual's own life and the trustee of that trust has an insurable interest under the second clause of section 2704(a) and section 2704(c)(5). In both scenarios, however, either the individual insured or the trustee must intend to purchase the policy for lawful insurance purposes, and not as a cover for a waging contract.

Where the individual insured creates a trust to hold a life insurance policy on his life and funds the trust with that policy or with money to pay its premiums then the trustee has the same insurable interest that the settlor has in his own life. Thus, we only inquire whether the owner (either the insured or the trust) has an insurable interest in the insured's life at the policy's inception and not whether the beneficiaries of the policy have an insurable interest. If the individual insured creates and initially funds the trust, then the trustee has an insurable interest without regard to how the trust beneficiaries obtained their interest.

Therefore, we answer Certified question three in the affirmative if the life insurance is procured for a legal purpose and not as a cover for an illegal wager contract. In cases where a third party either directly or indirectly funds the premium payments as part of a pre-negotiated arrangement with the insured to immediately transfer ownership, the policy fails at its inception for lack of an insurable interest.

***1079** *CONCLUSION*

For the above reasons, Certified Question one is answered in the affirmative, Certified Question two is answered in the negative and Certified Question three is answered in the affirmative.

All Citations

28 A.3d 1059

Footnotes

1 *PHL Variable Insurance Trust v. Price Dawe 2006 Insurance Trust,* C.A. No. 10–964–BMS (D.Del. Nov. 12, 2010) and *The Lincoln National Life Insurance Company v. Joseph Schlanger 2006 Insurance Trust,* C.A. No. 09–506–GMS, 2010 WL 2898315 (D.Del. July 20, 2010).

2 Supreme Court Rule 41(c)(iv), which concerns Certification of Questions of Law provides that only those facts contained in the certification are actually part of the record. D.R.S.C. Rule 41(c)(iv) ("The certification as filed shall constitute the record."). Nevertheless, the additional allegations from the plaintiffs' pleadings are included below in order to provide better context.

3 *CA, Inc. v. AFSCME Employees Pension Plan,* 953 A.2d 227, 231 (Del.2008).

4 *The Lincoln National Life Insurance Company v. Joseph Schlanger 2006 Insurance Trust,* C.A. No. 09–506–GMS, 2010 WL 2898315 (D.Del. July 20, 2010) also certified the first question to this court. Therefore, the answer and analysis for both questions will be the same.

5 The district court in *Schlanger* posed the question as, "Can a life insurer contest the validity of a life insurance policy based on a lack of insurable interest after expiration of the two-year contestability period set out in the policy as required by 18 *Del. C.* § 2908?"

6 Bertram Harnett & Irving I. Lesnick, *The Law of Life and Health Insurance* § 5.07 (Matthew Bender, Rev. Ed.2010).

7 Katherine Cooper, *Liar's Poker: The Effect of Incontestability Clauses After* Paul Revere Life Insurance Co. v. Haas, 1 Conn. Ins. L.J. 225, 228 (Spring 1995).

8 Erin Wessling, *Contracts—Applying the Plain Language to Incontestability Clauses,* 27 Wm. Mitchell L.Rev. 1253, 1256 (2000).

9 *Id.*

10 *Id.*

11 *See Penn Mut. Life Ins. Co. v. Oglesby,* 695 A.2d 1146, 1151 (Del.1997).

12 Wessling, *Contracts—Applying the Plain Language to Incontestability Clauses, supra* note 8 at 1257.

13 *Id.*

14 *Id.*

15 18 *Del. C.* § 2908 (2011).

16 *Id.* (emphasis added).

17 18 *Del. C.* § 2917 (emphasis added).

18 *See, e.g., Beard v. Am. Agency Life Ins. Co.,* 314 Md. 235, 550 A.2d 677, 689 (1988); *Wood v. New York Life Ins. Co.,* 255 Ga. 300, 336 S.E.2d 806, 811–12 (1985); *Commonwealth Life Ins. Co. v. George,* 248 Ala. 649, 28 So.2d 910, 912–14 (1947); *Henderson v. Life Ins. Co. of Va.,* 176 S.C. 100, 179 S.E. 680, 692 (1935); *Ludwinska v. John Hancock Mut. Life Ins. Co.,* 317 Pa. 577, 178 A. 28, 30 (1935); *Home Life Ins. Co. v. Masterson,* 180 Ark. 170, 21 S.W.2d 414, 417 (1929); *Bromley's Administrator v. Washington Life Ins.*

Co., 122 Ky. 402, 92 S.W. 17 (1906); *Harris v. Sovereign Camp Woodmen of the World,* 31 Ohio Law Abs. 317 (Ohio Ct.App.1940); *Goodwin v. Fed. Mut. Ins. Co.,* 180 So. 662, 665 (La.Ct.App.1938); *Charbonnier v. Chicago Nat'l Life Ins. Co.,* 266 Ill.App. 412 (Ill.App.Ct.1932). *But see, New England Mut. Life Ins. Co. v. Caruso,* 73 N.Y.2d 74, 538 N.Y.S.2d 217, 535 N.E.2d 270 (1989); *Bogacki v. Great–West Life Assurance Co.,* 253 Mich. 253, 234 N.W. 865 (1931).

19 *Dougherty v. Mieczkowski,* 661 F.Supp. 267, 274 (D.Del.1987) (citing Restatement (Second) Contracts § 163, 164 (1981)) (internal quotations and citations omitted).

20 *Id.*

21 *Sann v. Renal Care Centers Corp.,* 1995 WL 161458, at *5 (Del.Super.Ct.) (stating that "[a]s a general rule, agreements against public policy are illegal and void.... No agreement can be sustained if it is inconsistent with the public interest or detrimental to the public good.").

22 *Baltimore Life Ins. Co. v. Floyd,* 91 A. 653 (Del.Super.Ct.1914) (holding that where a party lacking an insurable interest procures a policy directly or by assignment on the life of another, "the transaction is a mere speculation ... contrary to public policy, and therefore void"), *aff'd* 94 A. 515, 520 (Del.1915); *Draper v. Delaware State Grange Mut. Fire Ins. Co.,* 91 A. 206, 207 (Del.Super.Ct.1914) (same).

23 *See Frank v. Horizon,* 553 A.2d 1199, 1205 (Del.1989) (holding that a contract provision that violates clear public policy is invalid as a matter of law).

24 *Bromley's Adm'r,* 92 S.W. at 18.

25 Our current case is distinguishable from *Oglesby. See Oglesby,* 695 A.2d at 1151. In *Oglesby,* this Court held the incontestability provision barred the insurer from contesting the validity of the contract based on misrepresentations in the insurance application related to pre-existing conditions. *Id.* This issue is resolvable by analyzing the nature of the fraud. Fraud relating to insurable interest is a fraud on the court because it violates the constitutional prohibition against wagering, and thus renders the contract void *ab initio*—a nullity. In contrast, basic fraud, such as misrepresentations in the application, renders the contract voidable subject to the contestability period.

26 *Caruso,* 535 N.E.2d at 273–74.

27 Susan Lord Martin, *Betting on the Lives of Strangers: Life Settlements, STOLI and Securitization,* 134 U. Pa. J. Bus. L. 173, 175 (2010).

28 *Id.*

29 *Id.*

30 *Id.* at 177.

31 *Warnock v. Davis,* 104 U.S. 775, 779, 26 L.Ed. 924 (1881) (emphasis added). *See also Grigsby v. Russell,* 222 U.S. 149, 154, 32 S.Ct. 58, 56 L.Ed. 133 (1911) ("A contract of insurance upon a life in which the insured has no interest is a pure wager that gives the insured a sinister counter interest in having the life come to an end.").

32 See Anthony Alt, *Spin–Life Insurance Policies: A Dizzying Effect on Human Dignity and the Death of Life Insurance,* 7 Ave Maria L.Rev. 605, 619–20 (2009); Kelly J. Bozanic, *An Investment to Die For: From Life*

Insurance to Death Bonds, the Evolution and Legality of the Life Settlement Industry, 113 Penn St. L.Rev. 229, 231, 234, 256 (2008).

33 Martin, 134 U. Pa. J. Bus. L. at 192–93.

34 DEL. CONST. art. II, § 17.

35 *Taylor v. Diamond State Port Corp.,* 14 A.3d 536, 538 (Del.2011) (citing *Dewey Beach Enters., Inc. v. Bd. of Adjustment,* 1 A.3d 305, 307 (Del.2010)).

36 *Id.*

37 *Id.*

38 *LeVan v. Indep. Mall, Inc.,* 940 A.2d 929, 933 (Del.2007) (quoting *Newtowne Vill. Serv. Corp. v. Newtowne Rd. Dev. Co.,* 772 A.2d 172, 175 (Del.2001)).

39 *LeVan,* 940 A.2d at 933 (quoting *Eliason v. Englehart,* 733 A.2d 944, 946 (Del.1999)).

40 *Taylor,* 14 A.3d at 538 (citing *Dewey Beach Enters.,* 1 A.3d at 307).

41 *Ins. Com'r. of State of Delaware v. Sun Life Assur. Co. of Canada,* 21 A.3d 15, 20 (2011) (citing *Eliason v. Englehart,* 733 A.2d 944, 946 (Del.1999)).

42 *Id.*

43 *A.W. Fin. Servs., S.A. v. Empire Res., Inc.,* 981 A.2d 1114, 1121 (Del.2009).

44 DEL. CONST. art. II, § 17.

45 *Grigsby,* 222 U.S. at 155, 32 S.Ct. 58.

46 *See Sun Life Assur. Co. of Canada v. Berck,* 770 F.Supp.2d 728 (D.Del.2011) (noting that insurable interest requirements are not satisfied where an insured takes out a policy in the beginning as a mere cover for a wager); *Principal Life Ins. Co. v. Lawrence Rucker 2007 Ins. Trust,* 735 F.Supp.2d 130, 140 (D.Del.2010), *reargument denied* (Nov. 1, 2010) (same); *Schlanger,* 2010 WL 2898315, at *7 (same); *Lincoln Nat'l Life Ins. Co. v. Snyder,* 722 F.Supp.2d 546, 558 (D.Del.2010) (same).

47 *See Grigsby,* 222 U.S. at 155, 32 S.Ct. 58 ("[C]ases in which a person having an interest lends himself to one without any, as a cloak to what is, in its inception, a wager, have no similarity to those where an honest contract is sold in good faith."); *Floyd,* 91 A. at 656 ("Where a third party, without any insurable interest in the life of another, procures a policy of insurance on the life of such person, either by having a policy issued directly to himself, *or by having the person whose life is insured take out a policy to himself, and then assign it,* these facts ... conclusively show that the transaction is a mere speculation on the life of another, and as such is contrary to public policy, and therefore void." (citation omitted) (emphasis added)).

48 *See, e.g.,* Phoenix Op. Br. at 21 ("The Trust would reduce insurable interest—the embodiment of the requirement that insurance insure against an actual risk, which is the essence of insurance—to a check box that could be satisfied by reference to paperwork drafter in a satisfactorily [sic.] manner.").

49 91 A. at 655–56; *aff'd* 94 A. 515, 520 (Del.1915).

50 *Id.*

51 *Id.* at 656.

52 *Id.*

53 56 Del. Laws, ch. 380, § 2704 (1967).

54 Admittedly, the General Assembly could have expressly stated "we abolish the concept of wagering contracts through the insurable interest requirement," or something similar. We, however, believe and the statute supports the fundamental concept against wagering contracts.

55 *Id.*

56 *A.W. Fin. Servs.,* 981 A.2d at 1121 (citing 15A C.J.S. *Common Law* § 16); *see also State v. Rogers,* 820 A.2d 1171, 1177 (Del.Super.2003).

57 *Id.; see also Norfolk Redevelopment and Hous. Auth. v. Chesapeake and Potomac Tel. Co. of Virginia,* 464 U.S. 30, 35, 104 S.Ct. 304, 78 L.Ed.2d 29 (1983) ("It is a well-established principle of statutory construction that [t]he common law ... ought not to be deemed repealed, unless the language of a statute be clear and explicit for this purpose.") (quotation marks omitted, ellipsis in original).

58 *Erie Railroad Co. v. Tompkins,* 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (1938) (holding that federal courts do not have the power to create general federal common law when hearing state law claims under diversity jurisdiction and accordingly must apply state substantive law in diversity cases).

59 *See Grigsby,* 222 U.S. at 154–55, 32 S.Ct. 58 (holding that person procuring a life insurance policy is required to have an "insurable interest"); *Warnock,* 104 U.S. at 779 (holding that contracts wagering on human life are against public policy); *Floyd,* 91 A. at 656 (holding that where a party lacking an insurable interest procures a policy directly or by assignment on the life of another, "the transaction is a mere speculation ... contrary to public policy, and therefore void"), *aff'd* 94 A. 515, 520 (Del.1915); *Draper v. Delaware State Grange Mut. Fire Ins. Co.,* 91 A. 206, 207 (Del.Super.Ct.1914) (same).

60 18 *Del. C.* § 2704(a).

61 *Id.*

62 *Id.* (emphasis added).

63 The General Assembly has expanded the class of persons who have an insurable interest in the life of the insured to reflect modern commercial developments and transactions relating to Corporate Owned Life Insurance and Trust Owned Life Insurance. 67 Del. Laws, ch. 161 (1989); 69 Del. Laws, ch. 462 (1994); 69 Del. Laws, ch. 462; 71 Del. Laws, ch. 239, § 2 (1998).

64 *Id.* Every individual has an insurable interest in his or her own life and all of the following have an insurable interest in the life of the individual insured: (1) individuals closely related by blood or law; (2) other persons who have a lawful and substantial economic interest in the continuance of the life of the insured and distinguished by an interest which only arises or would be enhanced by the death of the insured; (3) employers; (4) parties to a contract for the purchase or sale of a business interest; and (5) trustees of a trust established by an individual. 18 *Del. C.* § 2704(c)(1)-(5).

65 18 *Del. C.* § 2704(a).

66 18 *Del. C.* § 2720 ("A policy may be assignable or not assignable, *as provided by its terms.*" (emphasis added)).

67 *See also Grigsby,* 222 U.S. at 155, 32 S.Ct. 58 (holding an insured may assign a validly procured life insurance policy to a third party without an insurable interest).

68 15 N.Y.3d 539, 551, 914 N.Y.S.2d 709, 940 N.E.2d 535 (2010).

69 N.Y. Ins. Law § 3205(b)(1) ("Any person of lawful age may on his own initiative procure or effect a contract of insurance upon his own person for the benefit of any person, firm, association or corporation. *Nothing herein shall be deemed to prohibit the immediate transfer or assignment of a contract so procured or effectuated.*" (emphasis added)).

70 *See generally, Kramer,* 15 N.Y.3d 539, 914 N.Y.S.2d 709, 940 N.E.2d 535.

71 *See* N.Y. Ins. Law § 7815 (McKinney 2007) ("No person shall directly or indirectly engage in any act, practice or arrangement that constitutes stranger originated life insurance.").

72 18 *Del. C.* § 2705.

73 *Schlanger 2006 Ins. Trust,* CIV. 09–506–GMS, 2010 WL 2898315, at *6.

74 *Floyd,* 91 A. at 656.

75 *Rucker 2007 Ins. Trust,* 735 F.Supp.2d at 140.

76 *See Bussinger v. Bank of Watertown,* 67 Wis. 75, 30 N.W. 290, 294 (1886) (noting the benefits to the insured of the alienability of bona fide policies); *Clement v. New York Life Ins. Co.,* 101 Tenn. 22, 46 S.W. 561, 564 (1898) (voiding policy where insured had pre-arranged a deal to obtain the policy and transfer it to a third-party with no insurable interest immediately after issuance because "the transfer and assignment must be made in good faith, and not as a mere colorable evasion of the provision in regard to wagering contracts, [ ] in order to validate or legalize the same").

77 *See Chamberlain v. Butler,* 61 Neb. 730, 86 N.W. 481, 483 (1901) (finding that an assignment to one without an insurable interest is permitted where the transaction is "wholly independent of and subsequent to the" issuance of the policy, and that if the transfer "agreement had existed prior to the issuance of the policy, or contemporaneous therewith" the policy would be void).

78 *Clark v. Allen,* 11 R.I. 439, 440 (R.I. 1877).

79 *Floyd,* 91 A. at 655–56.

80 Supr. Ct. R. 15(a)(vi).

81 The synopsis of Senate Bill No. 83 addressing 18 *Del. C.* § 2704(c)(5) states:

> [I]t is intended to clarify the provisions of current law which state categorically that a trust has an insurable interest in the life of the person who creates the trust.

82 18 *Del. C.* § 2704(c)(5)(a)-(c), effective August 1, 2011.

83 44 Am.Jur.2d *Insurance* § 978 (2010) (citations omitted); *see* Richard A. Lord, 7 *Williston on Contracts* § 17.5 (4th ed.2010) ("[A] person may take out a policy on his own life, pay the premiums, and designate as a beneficiary any person he chooses, even though the beneficiary chosen would otherwise have no insurable interest in the life of the insured. Such a policy is not a wagering contract, unless the transaction is for the purpose of speculation and is mere cover for a wagering transaction.").

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133 F.Supp.3d 734
United States District Court, E.D. Pennsylvania.

IN RE: WELLBUTRIN XL ANTITRUST LITIGATION
This Document Relates to: All Actions

CIVIL ACTION NOS. 08-2431, 08-2433
|
Signed September 23, 2015

Synopsis

Background: Direct and indirect purchasers brought claims against producers and distributors of branded antidepressant drug under Sherman Act and state antitrust and consumer protection statutes, alleging they delayed entry of generic versions of drug to the American market by entering into illegal agreements with generic drug companies to settle patent infringement lawsuits. Defendants moved for summary judgment.

Holdings: The District Court, Mary A. McLaughlin, J., held that:

while fact that settlement allowed underlying patent litigation to continue did not exempt it from antitrust scrutiny, it was factor to be considered in rule of reason analysis;

even if plaintiffs had shown that settlement had anticompetitive effects, reasonable jury could not find that those effects outweighed settlement's procompetitive benefit; and

plaintiffs could not prove that they suffered antitrust injury or that settlement was the proximate cause of any injury suffered.

Motion granted.

Procedural Posture(s): Motion for Summary Judgment.

***736** MEMORANDUM

McLaughlin, District Judge

This lawsuit is one of many in the federal courts involving the application of the Supreme Court's decision in FTC v. Actavis, Inc., —— U.S. ——, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013), to settlements between branded and generic pharmaceutical manufacturers. In this case, direct and indirect purchasers of Wellbutrin XL have brought ***737** claims under the Sherman Act and state antitrust and consumer protection statutes, alleging that the defendants SmithKline Beecham Corporation d/b/a GlaxoSmithKline and GlaxoSmithKline plc (collectively, "GSK") delayed the entry of generic versions of Wellbutrin XL to the American market by entering into illegal agreements with generic drug companies to settle patent infringement lawsuits.

In Actavis, the Supreme Court held that settlements in which the holder of a pharmaceutical patent makes a payment to an alleged patent infringer to resolve a challenge to the patent—so-called "reverse payment settlements" [1] —"can sometimes violate the antitrust laws." Actavis, 133 S.Ct. at 2227. The Supreme Court explained that such settlements are neither presumptively unlawful nor presumptively lawful, and instructed district courts to evaluate the settlements under the long-standing rule of reason framework. Id. at 2237–38. Reverse payment settlements, the Court cautioned, could present the following anticompetitive harm: eliminating "the risk of patent invalidation or a finding of non-infringement" that the underlying patent lawsuit presented. Id. at 2236–37.

The settlements challenged in this case (collectively the "Wellbutrin Settlement") resolved patent disputes among GSK, GSK's business partner Biovail, and multiple generic manufacturers who had filed Hatch-Waxman Act Paragraph IV Certifications challenging the Wellbutrin XL patent. The Wellbutrin Settlement, reached in February 2007, allowed the underlying Hatch-Waxman litigation to continue, and provided for entry of generic Wellbutrin XL immediately upon a finding of non-infringement or patent invalidity, and in any case no later than May 30, 2008, 10 years before the expiration of the patent. The settlement also granted the generic manufacturers sublicenses to patents (which expired in 2022) at issue in a separate patent lawsuit, and provided a guaranteed generic supply of Wellbutrin XL; it also provided for enhanced review of the settlement by the Federal Trade Commission. In the settlement, GSK agreed not to launch an authorized generic Wellbutrin XL product during the generic manufacturer's period of Hatch-Waxman guaranteed exclusivity.

GSK has filed three motions for summary judgment: one motion for summary judgment as to all claims made by the plaintiffs; one motion for summary judgment addressing only

the issue of causation; and one motion for summary judgment as to the indirect plaintiffs' Cartwright Act cause of action. In connection with its motions for summary judgment, GSK has filed Daubert motions to exclude the plaintiffs' experts. In addition to their oppositions to GSK's motions for summary judgment, the plaintiffs have filed Daubert motions to exclude GSK's expert Dr. Martin Adelman. The court will grant summary judgment to GSK.

The series of settlement agreements challenged here contains a provision not present in any other post-Actavis case of which the Court is aware: the generic manufacturer did not abandon its challenge to ***738** the patent held by GSK's business partner, Biovail. The settlement provided that if the generic manufacturer prevailed on its appeal in the Federal Circuit, it could immediately enter the market with generic Wellbutrin XL. GSK, therefore, argues that the Wellbutrin Settlement does not come within the purview of Actavis and should be exempt from antitrust scrutiny. The Court is reluctant to apply such a mechanical test, because it could offer blanket immunity to any reverse payment settlement in which the underlying patent litigation continues; this could create an easily exploited loophole. The Supreme Court in Actavis—and antitrust law historically—rejects such a formalistic approach to evaluating an agreement.

The fact that the Wellbutrin Settlement allowed the underlying patent litigation to continue, however, is a factor to be considered in the rule of reason analysis mandated by Actavis. The plaintiffs cannot establish the anticompetitive harm contemplated by Actavis: that the defendant in the patent infringement lawsuit would abandon its patent claim, eliminating the risk of patent invalidation or a finding of non-infringement. The plaintiffs' necessary alternate theory of anticompetitive harm is that the Wellbutrin Settlement delayed the launch of a generic product. But the plaintiffs have not established a proper foundation for such a claim by showing either that an alternate settlement would have been reached absent a no authorized generic agreement, or that continued litigation would have resulted in earlier generic entry through an at risk launch.

As to a settlement without a no authorized generic provision, there is no evidence that such a settlement was ever contemplated, much less that it would have resulted in an earlier entry date. The summary judgment record shows that the generic manufacturers regarded the no authorized generic agreement as an essential term. As to continued litigation and the at risk launch, the plaintiffs have not made an adequate showing that a separate patent would not have been an independent bar to market entry.

Even if the plaintiffs had shown that the Wellbutrin Settlement had anticompetitive effects, the Court finds that a reasonable jury could not find that any anticompetitive effects outweigh the procompetitive benefits of the settlement. The Wellbutrin Settlement provided sublicenses to a generic patent that was the subject of separate infringement actions brought by a different pharmaceutical company, and obligated Biovail to supply the generic manufacturer with generic Wellbutrin XL, two results not achievable through successful litigation alone.

Finally, the plaintiffs cannot prove that they suffered antitrust injury or that the Wellbutrin Settlement was the proximate cause of any injury suffered because they have not presented evidence that the Wellbutrin Settlement, as opposed to an independent patent, prevented market entry of generic Wellbutrin XL.

I. Summary Judgment Record [2]

The settlement agreement at issue in these cases—the Wellbutrin Settlement—involves the interplay between complex ***739** statutory and regulatory schemes, multiple patent infringement lawsuits, and extensive negotiations among numerous parties. The Court has addressed each factual issue individually below.

A. The Drug Approval Process and Regulatory Framework

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–92 ("FDCA"), provides that the Food and Drug Administration ("FDA") must approve all drugs before they may be introduced into interstate commerce. Companies seeking to market drugs must file applications for approval under one of two procedures.

Under the first procedure, a new drug (or "brand name" drug) applicant files a New Drug Application ("NDA"), which must include examples of the proposed labeling for the drug and clinical data demonstrating the drug's safety and efficacy. The NDA must also include the patent number and expiration date of any patent that claims either the drug or a method of using the drug if "a claim of patent infringement could reasonably be asserted." Submission of an NDA involved "a long, comprehensive, and costly testing process." Actavis, 133 S.Ct. at 2228. The FDA publishes the names of approved

drugs and their associated patents in what is commonly known as the "Orange Book."[3] 21 U.S.C. § 355(a),(b).

Congress established the second new drug approval procedure in 1984 with the Drug Price Competition and Patent Term Restoration Act (the "Hatch–Waxman Act"). Pub.L. No. 98–417, 98 Stat. 1585 (1984). The Hatch–Waxman Act allows companies seeking to manufacture and market a generic version of a previously approved pioneer drug (known as the "listed drug") to avoid filing an NDA. Instead, generic manufacturers are permitted to file an Abbreviated New Drug Application ("ANDA"). The ANDA permits the applicant to rely on the safety and efficacy data for the listed drug if the applicant can show that the generic product is "bioequivalent" to the listed drug. 21 U.S.C. §§ 355(j)(2)(A)(iv), (j)(8)(B).

As part of the ANDA process, a generic manufacturer must make one of four certifications regarding each patent associated in the Orange Book with the listed drug: (I) that the patent information has not been filed; (II) that the patent has expired; (III) that the patent is set to expire; or (IV) that the patent is invalid or will not be infringed by the generic drug. This fourth certification is known as a "Paragraph IV Certification." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A generic manufacturer that files a Paragraph IV Certification must give notice to the patent holder and provide a "detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B).

The Hatch–Waxman Act provides that if the patent holder files an infringement suit within 45 days after receiving notice of the Paragraph IV Certification, the patent holder benefits from a statutory stay on FDA approval of the ANDA for a period of 30 months or until the resolution of the infringement suit, whichever is shorter. 21 U.S.C. § 355(j)(5)(B)(iii). If the generic applicant begins to market its generic product prior to a determination of the patent's validity or scope, the launch is considered to be "at risk" and the manufacturer can be forced to pay damages. See 35 U.S.C. 271(e)(4)(C).

The first generic company to file an ANDA containing a Paragraph IV Certification ***740** (the "first filer") also receives an "exclusivity" period of 180 days during which the FDA may not approve any later-filed paragraph IV ANDA based on the same NDA. *Id.* § 355(j)(5)(B)(iv). The 180–day period begins to run from either the date that the first filer begins to market its drug or the date of a final judgment that the patent is invalid or not infringed, whichever is earlier. Id. §§ 355(j)(5)(B)(iv), 355(j)(5)(D). The patent holder, however, is not barred from marketing an authorized generic product during the 180-day period. See King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388, 393 (3d Cir.2015); Pls. Ex. 943.

B. Wellbutrin Products & Patents

The product at issue in this litigation is Wellbutrin XL, the third iteration of GSK's Wellbutrin product.

Bupropion hydrochloride, an active pharmaceutical ingredient used to treat depression, was first approved by the FDA for the treatment of major depressive disorder in 1985 in an immediate release formulation known by its branded name, Wellbutrin IR. Wellbutrin IR provides for rapid release of the active ingredient and is taken three times a day. To reduce the degradation of bupropion hydrochloride upon contact with water, GSK added hydrochloric acid as a stabilizing agent. GSK Stmt. ¶ 1-2; Pls.' Stmt. Opp. ¶ 1-2.

The next bupropion hydrochloride product to reach the market was the sustained release Wellbutrin SR, which is taken twice a day. Wellbutrin SR was approved on the basis of its bioequivalence to Wellbutrin IR. Wellbutrin SR also used hydrochloric acid as a stabilizing agent. GSK Stmt. ¶ 1-2; Pls.' Stmt. Opp. ¶ 1-2.

Biovail acquired the rights to two U.S. patents covering extended release formulations of bupropion hydrochloride: U.S. Patent No. 6,096,341 (the "'341 patent") and U.S. Patent No. 6,143,327 (the "'327 patent"). Both patents are set to expire on October 30, 2018. GSK Stmt. ¶ 5; Pls.' Stmt. Opp. ¶ 5.

In 2001, Biovail and GSK entered into an agreement to develop, manufacture, and promote a once-a-day extended release bupropion hydrochloride (the "Co-Promotion Agreement"). The extended release formulation, brand-named Wellbutrin XL, would be taken once a day and allow for the continuous and slow release of bupropion hydrochloride into the bloodstream over time. GSK had not independently developed an extended release version of bupropion hydrochloride. The FDA approved GSK's Wellbutrin XL NDA in August 2003. GSK Stmt. ¶ 3, 5-6; Pls.' Stmt. Opp. ¶ 3, 5-6.

C. The Underlying Patent Litigations

There are two sets of underlying patent litigations relevant to the antitrust questions presented by the Wellbutrin Settlement: the cases between Biovail and the generic manufacturers that filed Paragraph IV Certifications (the "Biovail Litigations")—specifically the Anchen litigation and the cases between Andrx Pharmaceuticals and GSK and Anchen Pharmaceuticals, respectively (the "Andrx Litigations").

1. The Biovail Litigations

Between September 2004 and May 2005, four generic manufacturers—Anchen Pharmaceuticals, Inc. ("Anchen"), Abrika Pharmaceuticals, LLP ("Abrika"), Impax Laboratories, Inc. ("Impax"), and Watson Pharmaceuticals, Inc. ("Watson")—filed Abbreviated New Drug Applications ("ANDAs") with the FDA, seeking approval for generic versions of Wellbutrin XL. Each generic manufacturer filed a Paragraph IV Certification claiming non-infringement and served GSK and Biovail with that Certification; the Certifications provided notice of the ANDA filing and declared ***741** that the generic product would not infringe Biovail's patents. The Paragraph IV Certifications triggered the 45-day window provided by the Hatch-Waxman Act for filing a patent infringement action. GSK Stmt. ¶ 7-9; Pls.' Stmt. Opp. ¶ 7-9.

In each case, Biovail filed a lawsuit against the generic manufacturers; GSK initially joined the lawsuits against Anchen and Abrika but withdrew from both cases in April 2005.[4] Biovail and GSK's December 21, 2004 lawsuit against Anchen, the first generic ANDA filer, triggered the 30-month stay in final FDA approval provided by the Hatch-Waxman Act. GSK Stmt. ¶ 10-11; Pls.' Stmt. Opp. ¶ 10-11.

Biovail's Hatch-Waxman lawsuit against Anchen is the case particularly relevant for evaluating the Wellbutrin Settlement, because only the settlement of the Anchen litigation involved any alleged reverse payment.

Anchen's ANDA did not quantify the amount of hydrochloric acid in its product on a per unit basis. The ANDA described a product that used hydrochloric acid as a "stabilizing agent" in the manufacturing process, but stated that the acid was "evaporated during processing" and indicated a "-" under the column designated "MG PER TABLET." Similarly, the percentage of hydrochloric acid was listed as "-" and ingredients other than hydrochloric acid were shown in the ANDA to add up to 100.0% of the finished product. A list in the ANDA comparing the Anchen product to Wellbutrin XL did not include hydrochloric acid as an ingredient in Anchen's product. GSK Stmt. ¶ 12-13; Pls.' Stmt. Opp. ¶ 12-13.

In the Anchen litigation[5], Anchen and Biovail disputed the proper claim construction of the term "free of stabilizer", as used in Biovail's patent '341 patent. Anchen argued that the term "free of stabilizer" means the tablet is "free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet." In contrast, Biovail argued that "free of stabilizer" meant that "the core lacks an effective stabilizing amount of an organic or inorganic acid capable of inhibiting the degradation of bupropion hydrochloride....." GSK Stmt. ¶ 12-13; Pls.' Stmt. Opp. ¶ 12-13.

On February 8, 2006, Judge Selna issued a Claim Construction Order finding that "free of stabilizer" meant that "the core is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet." Regarding Biovail's claim construction argument, Judge Selna's order stated:

> Biovail's proposed definition of "stabilizer" is not found anywhere in the '341 patent, and actually contradicts the summary of the invention.

GSK Stmt. ¶ 13; Pls.' Stmt. Opp. ¶ 13; Am. Order on Cl. Constr. Hr'g 9.

The parties filed cross motions for summary judgment following Judge Selna's ruling on claim construction. In addition to its claim construction argument, Biovail argued (1) that it was entitled to rely on the representations in Anchen's ANDA when initiating suit and (2) that Anchen had an obligation under FDA regulations and guidance to quantify even residual amounts of hydrochloric acid ("HCl") if the HCI tended to stabilize the final tablet, which it had not done. Biovail argued, therefore, that Anchen's ANDA controlled the infringement inquiry and suggested ***742** that Anchen's product was not "free of stabilizer" as Judge Selna had determined.[6] GSK Stmt. ¶ 14; Pls.' Stmt. Opp. ¶ 14; In re Wellbutrin XL Antitrust Litig., 2012 WL 1657734 at *10–11 (E.D.Pa. May 11, 2012).

Judge Selna issued a tentative minute order denying Anchen's motion, finding a genuine issue of material fact regarding whether Anchen's ANDA directly addressed the infringement inquiry. GSK Stmt. ¶ 14; Pls.' Stmt. Opp. ¶ 14.

After oral argument, however, Judge Selna granted Anchen's motion for summary judgment on August 1, 2006. The court found that there were no facts to show that Anchen's product was "free of stabilizer" since Anchen's product contained the stabilizer hydrochloric acid. Judge Selna denied Biovail's motion for reconsideration, and entered judgment on August 25, 2006. Biovail appealed to the Federal Circuit, challenging both the claim construction and summary judgment orders. Biovail's appeal was docketed on September 25, 2006. GSK Stmt. ¶ 14-15; Pls.' Stmt. Opp. ¶ 14-15.

Following full briefing, the Federal Circuit held oral argument on September 5, 2007. During oral argument, the Federal Circuit engaged in extensive questioning of Anchen's counsel regarding whether Anchen was required to list the amount of "stabilizing" hydrochloric acid in a tablet of generic Wellbutrin XL if the hydrochloric acid was serving a function in the tablet. As the Court recognized in granting summary judgment on the plaintiffs' sham litigation claims, the panel asked whether Anchen had complied with FDA regulation. GSK Stmt. ¶ 15, 16, 19; Pls.' Stmt. Opp. ¶ 15, 16, 19; Anchen Fed. Cir. Tr. at 16-17; In re Wellbutrin XL Antitrust Litig., 2012 WL 1657734 at *10 n. 10 (E.D.Pa. May 11, 2012).

The Federal Circuit granted Biovail's motion to withdraw its appeal on June 11, 2008. GSK Stmt. ¶ 15, 19; Pls.' Stmt. Opp. ¶ 15, 19; Order Granting Mot. to Withdraw.

2. The Andrx Litigations

The litigations among Biovail and the generic manufacturers were not the only patent infringement actions impacting the marketing of both branded and generic 150mg Wellbutrin XL: both GSK and Anchen faced patent infringement actions by Andrx Pharmaceuticals ("Andrx").

***743** On December 21, 2005, Andrx filed a patent infringement lawsuit against GSK, claiming that GSK's 150mg Wellbutrin XL product infringed Anchen's '708 patent. Andrx sought treble damages and an injunction preventing the sale of the allegedly infringing products. As a defense, GSK argued that the Andrx patent was invalid and that Andrx's inequitable conduct should prevent its recovery. The parties' motions for summary judgment were pending when the case settled in February 2007. Under the settlement, GSK paid Andrx $35 million for past use of the allegedly infringing technology and an ongoing royalty for future use. GSK Stmt. ¶ 44; Pls.' Stmt. Opp. ¶ 44; Andrx Pharms. V. GlaxoSmithKine, PLC, No. 05-23264 (S.D. Fla.); GSK Exs. 5, 18, 21-22.

On November 28, 2006, Andrx filed a patent infringement lawsuit against Anchen, claiming that Anchen's generic 150mg Wellbutrin Xl product would infringe Andrx's '708 patent. Andrx sought both preliminary and permanent injunctions to prevent the sale of generic Wellbutrin XL. [7] The district court in Andrx had denied Andrx's motion for a temporary restraining order but had not ruled on Andrx's motion for a preliminary injunction at the time the settlement was reached; the parties were still briefing the preliminary injunction issues. Andrx Pharms. v. Anchen Pharms., No. 06-7552 (C.D. Cal); GSK Ex. 23; Pls. Ex. 858; GSK Stmt. ¶ 45; Pls.' Stmt. Opp. ¶ 45.

Anchen was limited in its ability to defend the patent infringement lawsuit: Anchen's CEO, Chih-Ming Chen, was the inventor of the Andrx patent and had assigned the patent rights to Andrx. Anchen's marketing partner Teva Pharmaceuticals U.S.A., Inc. ("Teva") had therefore recognized that the doctrine of "inventor estoppel would prevent Anchen from raising an argument as to the invalidity of the '708 patent," which was the defense used by GSK. GSK Stmt. ¶ 82; Pls.' Stmt. Opp. ¶ 82; Holding Dep. Tr. 65:3-19.

The Andrx lawsuits were settled as part of the Wellbutrin Settlement, discussed below. GSK Stmt. ¶ 45; Pls.' Stmt. Opp. ¶ 45.

D. Biovail's Citizen Petition [8]

On December 20, 2005, Biovail filed a citizen petition with the FDA; GSK did not join the filing. The citizen petition requested that the FDA require any ANDA for a generic version of Wellbutrin XL to meet four criteria: (1) all bioequivalence trials should calculate and evaluate parameters based on concentrations of the parent drug and active metabolites; (2) any generic formulation should be shown to be bioequivalent to Wellbutrin XL, sustained release and immediate release bupropion; (3) the bioequivalence studies should be conducted at steady-state evaluating the performance of the dosage form based on AUC, Cmax, Cmin;

and (4) data using the FDA's approach for evaluating the effect of alcohol on the performance of the controlled-release dosage form should be required to ensure the absence of "dose dumping." The FDA granted in part and denied in part the citizen petition. GSK Stmt. ¶ 45; Pls.' Stmt. Opp. ¶ 45; In re Wellbutrin XL Antitrust Litig., 2012 WL at 1657734 *21.

***744** E. Anchen/Teva's Production of Generic Wellbutrin

Anchen qualified for the Hatch-Waxman Act's 180-day exclusivity period for generic Wellbutrin XL because it was the first to file an ANDA with the FDA. [9] Anchen waived its exclusivity for 300mg Wellbutrin XL in favor of Impax. [10] In December 2006, Anchen and Teva entered a Distribution and Supply Agreement that authorized Teva to market Anchen's 150mg version of generic Wellbutrin XL. The agreement required Teva to launch generic Wellbutrin XL no later than the later of 14 days after Anchen received final FDA approval or thirty days after Teva received the product for launch. GSK Ex. 2; Pls. Ex. 844; GSK Stmt. ¶ 20, 26; Pls.' Stmt. Opp. ¶ 20, 26.

Anchen and Teva had discussed the possible at risk launch of 150mg generic Wellbutrin XL, anticipating a launch in the first quarter of 2007. Pls. Exs. 772, 813, 846, 922, 899, 915, 770.

In December 2006, the FDA approved Anchen's ANDA for both the 300mg and 150mg versions of generic Wellbutrin XL. Anchen's ANDA listed its Goodyear facility as the intended manufacturing site for its generic Wellbutrin XL product. GSK Stmt. ¶ 22-25; Pls.' Stmt. Opp. ¶ 22-25.

During the FDA's January 2007 inspection of Anchen's Goodyear manufacturing site, the FDA learned for the first time that Anchen was expecting to use its Jeronimo manufacturing site—rather than the Goodyear manufacturing site—to manufacture its generic Wellbutrin XL product. GSK Ex. 72.

On May 29, 2007, Anchen received the FDA's Establishment Inspection Report from the January 2007 Goodyear facility inspection. The report explained that the change involving the inspection facility "would require a prior approval supplement if the facility had never been inspected by FDA," as was the case with Anchen's Jeronimo facility. [11] The FDA told Anchen that it could provide notice of its manufacturing facility change through a "Changes Being Effected in 30 Days" supplement, known as a "CBE-30". Anchen filed a CBE-30 to add the Jeronimo facility to its ANDA on June 1, 2007; on June 9, 2007, Anchen provided the FDA with requested drug-release stability data. GSK Stmt. ¶ 31-42; Pls.' Stmt. Opp. ¶ 31-42; GSK Exs. 72, 74.

The FDA orally accepted Anchen's CBE-30 on June 11, 2007. This acceptance was effective on June 12, 2007. Anchen could not market generic Wellbutrin XL ***745** until the FDA accepted Anchen's CBE-30. Choy Dep. Tr. 32:14-33:2; GSK Ex. 75.

F. The Wellbutrin Settlement

The Wellbutrin Settlement was executed on February 9, 2007 and resolved the Wellbutrin XL Hatch-Waxman litigations brought by Biovail against generic manufacturers Teva, Anchen, Impax, and Watson, as well as the patent litigation brought by Andrx against the generic manufacturers. The Wellbutrin Settlement was comprised of multiple agreements: the Omnibus Agreement (in which GSK was listed as an intended third party beneficiary); the Anchen Definitive Agreement; the Teva License Agreement; the Impax Settlement Agreement; and the Third Amendment, an agreement between GSK and Biovail by which GSK relinquished its right to launch an authorized generic during the 180-day exclusivity period provided by the Hatch-Waxman Act. GSK Stmt. ¶ 52, 54; Pls.' Stmt. Opp. ¶ 52, 54.

The following lawsuits were pending at the time of the Wellbutrin Settlement: Biovail's appeal of the summary judgement decision in the Anchen litigation; the Watson, Impax, and Abrika [12] lawsuits brought by Biovail; the Andrx lawsuits brought against GSK and Anchen; and the action filed by Biovail against the FDA pertaining to its Citizens Petition (in which Teva, Anchen, and Impax had intervened as defendants). Biovail Labs., Inc. v. Anchen Pharms., Inc., 06-1641 (Fed. Cir.); Biovail Labs. Int'l SRL v. Watson Labs, Inc., No. 05-7799 (S.D.N.Y.); Biovail Labs. Int'l SRL v. Impax Labs. Inc., No. 05-1085 (E.D. Pa.); Biovail Labs., Inc. and SmithKline Beecham Corp. v. Abrika, LLP, et al., No. 04-61704 (S.D. Fla.); Andrx Pharms. v. GlaxoSmithKline, PLC, No. 05-23264 (S.D. Fla.); Andrx Pharms, LLC v. Anchen Pharms., Inc., No. 06-07552 (C.D. Ca.); Minute Orders, Biovail Corp. v. U.S. Food & Drug Admin., No. 06-1487 (D.D.C. Aug. 24, 2006 and Jan. 2, 2007) (granting Teva, Anchen, and Impax's unopposed motions to intervene as defendants). Biovail's appeal of the Anchen litigation

remained pending following the execution of the Wellbutrin Settlement. GSK Stmt. ¶ 53; Pls.' Stmt. Opp. ¶ 53.

The Wellbutrin Settlement was initially negotiated among Biovail, Teva, Anchen, and Impax without GSK's involvement, with Teva taking the lead in negotiating for the generic manufacturers. GSK became directly involved in the settlement discussions in December 2006: at a December 20 and 21 hearing in the Impax Hatch-Waxman litigation, the Honorable Anita B. Brody, who was presiding over the Impax litigation, requested that GSK participate based on the parties' representation that GSK was necessary to resolving the litigation because of its exclusive rights to market an authorized generic of Wellbutrin XL. [13] GSK Stmt. ¶ 56-57, 59; Pls.' Stmt. Opp. ¶ 56-57, 59; Brannon Dep. Tr. 131:17-132:6 ***746** ("[T]here was a federal Judge saying 'I need you to show up, and I need you to work with these parties to make a settlement possible.").

Following Judge Brody's request, GSK joined the settlement discussions. Following settlement discussions, GSK agreed to cede licensing and manufacturing rights to its authorized generic Wellbutrin XL. GSK also agreed to sublicense the Andrx patent license to Biovail. Initially, GSK was only willing to finalize the agreement if Judge Brody found the Wellbutrin Settlement procompetitive; GSK, ultimately acquiesced on this point, however, when Judge Brody refused to review the settlement. GSK Stmt. ¶ 60-63, 65; Pls.' Stmt. Opp. ¶ 60-63, 65; Brannon Dep. Tr. 190:17-191:4; GSK Ex. 62.

Both parties have recognized that the Wellbutrin Settlement was a complex agreement with numerous provisions. [14] The following provisions are at issue in this action:

1. The Wellbutrin Settlement Allowed the Anchen Litigation to Continue

The Wellbutrin Settlement allowed the Anchen litigation, which was on appeal in the Federal Circuit when the settlement was reached on February 9, 2007, to continue. At the time the Wellbutrin Settlement was reached, the appeal was not fully briefed oral argument on the Anchen appeal was scheduled for September 2007. [15] GSK Stmt. ¶ 68; Pls.' Stmt. Opp. ¶ 68.

2. Regardless of the Outcome of the Anchen Litigation, the Wellbutrin Settlement Allowed Generic Entry No Later Than May 30, 2008

The Wellbutrin Settlement provided that Teva could enter the market with generic Wellbutrin XL immediately upon Anchen prevailing in its underlying patent litigation (either through a showing of patent invalidity or a showing of non-infringement, or on May 30, 2008, whichever date was earlier. [16] The Wellbutrin Settlement allowed Teva to market generic Wellbutrin XL on May 30, 2008, even if Biovail won its appeal. GSK Ex. 6 at 3.16; GSK Stmt. ¶ 68; Pls.' Stmt. Opp. ¶ 68; Cremieux Dep. Tr. 335:12-24.

Although internal GSK and Biovail documents recognized that the May 30, 2008 entry date was the most "likely" outcome, all documents simultaneously recognized that there were "defined exceptions" to that date, including the exception of an Anchen litigation victory. [17] Id.; Pls. Exs. 857, 589, 805, 821, 771.

3. The Wellbutrin Settlement Included a "No Authorized Generic" Promise

The Wellbutrin Settlement guaranteed Teva the exclusive right to sell 300mg generic Wellbutrin XL (which Teva had launched at risk) from December 13, 2006 ***747** through June 12, 2007, and included an agreement that GSK would not market an authorized generic 150mg Wellbutrin XL until Anchen's 180-day exclusivity period expired. Because GSK had the sole authority to decide whether to pursue an authorized generic, GSK's agreement was necessary to effectuate the no authorized generic promise in the Wellbutrin Settlement. GSK Stmt. ¶ 56, 65, 75; Pls.' Stmt. Opp. ¶ 56, 65, 75.

One constant throughout the negotiations was Teva's insistence that any settlement involve an agreement that GSK not produce an authorized generic version of Wellbutrin XL during the 180-day exclusivity period. Teva's representatives expressed the (mistaken) view that the Hatch-Waxman 180-day exclusivity period had been designed to ensure that no authorized generic would be marketed during that time period. [18]

For example, a Stipulation and [Proposed] Order that was drafted but ultimately not submitted to the court by the parties to the Impax litigation noted that the parties tried to negotiate a settlement without an exclusive license to Teva during the first 180 days but "[w]ithout this provision, there would be no settlement of this matter." All drafts of the Wellbutrin Settlement included the no authorized generic agreement. GSK Stmt. ¶ 61-63, 77-78; Pls.' Stmt. Opp. ¶ 61-63, 77-78; Brannon Dep. Tr. 129:14-130:5 ("Teva...was very adamant that there were certain issues that were deal breakers for them, and they required GSK to waive certain rights if there was going to be any settlement at all."); Brannon Dep. Tr. 96:14-16 ("Teva informed us that there could be no settlement of the litigation unless GSK waived back to Biovail the right to launch an authorized generic."); Brannon Dep. Tr. 96:20-97:8 ("Teva stated it would not settle the litigation unless GSK waived its right to launch an authorized generic during the first 180 days of generic entry.").

4. The Wellbutrin Settlement Resolved the Andrx Litigations and Granted Anchen a Sublicense for the Andrx Patent

The Wellbutrin Settlement included sublicenses through Biovail to the license GSK obtained from Andrx with regard to the 150 mg product for each of the generic manufacturers. Teva took the position during the negotiation of the Wellbutrin Settlement that it needed "the full freedom to operate" without concern over patent infringement claim by Andrx. Additionally, because Anchen's CEO, Chih-Ming Chen, was the inventor of the Andrx patent (he had left Andrx to found Anchen), Teva had expressed concern that the theory of inventor estoppel would prevent Anchen from raising an argument as to the invalidity of the '708 patent in the Andrx v. Anchen litigation. GSK Stmt. ¶ 80-82; Pls.' Stmt. Opp. ¶ 80-82.

GSK and Andrx had settled the Andrx litigation during negotiation of the Wellbutrin Settlement. GSK agreed to pay $35 million in full satisfaction of Andrx's claims for sales of Wellbutrin XL occurring prior to February 1, 2007, and a 3.5% royalty of its net sales after February 1, 2007. Essential for Anchen, the settlement agreement also gave GSK the right to grant a sublicense of the Andrx '708 patent to Biovail, which could then sublicense the '708 patent to the generic companies which would pay a royalty to Andrx. The sublicense provisions made it unnecessary for Anchen, Teva, and Andrx independently to settle the Andrx v. Anchen litigation and ensured that Anchen and Teva would not be prevented from launching their generic Wellbutrin ***748** XL.[19] Teva had expected that GSK's settlement with Andrx would include the sublicense provisions. GSK Stmt. ¶ 46-47; Pls.' Stmt. Opp. ¶ 46-47; GSK Ex. 5, 64.

Anchen, Teva, and Andrx communicated regarding a possible settlement to the Andrx litigation.[20] Teva was explicit in those communications that any discussions were "subject to the overall deal process" of the Wellbutrin Settlement. Pls.' Stmt. Opp. ¶ 45; Pls. Ex. 864.

5. Biovail Agreed to Guarantee Teva a Supply of Wellbutrin XL

The Wellbutrin Settlement also included a supply provision that required Biovail to supply Teva with Wellbutrin XL if (1) Teva faced limited supply from Anchen or (2) the FDA ruled on Biovail's citizen petition in a way that made generic Wellbutrin XL non-compliant. Biovail was obligated to provide up to 75 million pills if Anchen faced supply issues, and an unlimited amount of pills if the outcome of the citizen petition made generic Wellbutrin XL non-compliant. The supply option would provide Teva with access to immediate supply of Wellbutrin XL if Anchen prevailed on appeal and Teva was allowed to enter the market. GSK Stmt. ¶ 69, 73; Pls.' Stmt. Opp. ¶ 69, 73.

Teva requested that the backup supply provision be generous because Teva "need[ed] to be able to sell on the trigger date," which "require[d] reasonable preparations".[21] Teva's 30(b)(6) witness testified that "as a business matter" it made sense to include the supply provision because Teva would not want to have uncertainty in supply to patients. The supply provision was extensively negotiated among GSK, Biovail, and the generic manufacturers. Bauer Dep. Tr. 100:3-7, 112:18-21; Pls. Ex. 886; GSKWXLC00000808; BIOVAIL0630819; TEVA_WXL08669.

6. The Wellbutrin Settlement Also Contained Provisions for Enhanced FTC Review

Under the provisions of the Medicare Modernization Act Section 1112(a) of Subtitle B of Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), parties to a reverse payment patent litigation

settlement are required to submit the settlement agreement and all related agreements to the FTC within 10 business days of entry of the agreement.

The Wellbutrin Settlement required the parties to submit the agreement to the Federal Trade Commission ("FTC") for review within two days of finalizing the agreement. The parties to the settlement were also required to respond to any FTC inquiries, and if the FTC raised any concerns about the settlement to either revise the settlement as directed by the FTC or ***749** terminate the agreement. GSK had equal rights to all other parties to the agreement to terminate the Wellbutrin Settlement if it faced FTC challenges. GSK Stmt. ¶ 85-86; Pls.' Stmt. Opp. ¶ 86-86.

On February 20, 2007, after submitting the Wellbutrin Settlement to the FTC, Biovail, Anchen, Teva, and Impax met with senior FTC counsel to review the terms of the agreements. Biovail and the generic companies provided the FTC with a total of twenty four documents that comprised the Wellbutrin Settlement, as well as a list of parties to the transaction, the patents asserted, and the lawsuits involved. The parties did not provide a written summary of the agreements for the FTC. GSK Stmt. ¶ 87; Pls.' Stmt. Opp. ¶ 87.

At the meeting, the parties presented the central features of the Wellbutrin Settlement to the FTC: (i) the back-up supply provision to Teva (including the provision that allowed for supply in the event of an impediment as a result of Biovail's citizen petition); (ii) the Andrx sublicenses to Teva, Anchen, and Impax; and (iii) the early trigger date for the 150 mg product in the event the Anchen appeal was decided in Anchen's favor prior to the negotiated May 30, 2008 date. During the meeting, Teva's antitrust counsel explained to the FTC that the Wellbutrin Settlement "relieved Teva of the potential enormous liability that" launching the 300mg product at risk in December 2006 had created. Teva's counsel explained to the FTC that this feature distinguished the Wellbutrin Settlement "from a typical Hatch-Waxman settlement" and, as a result, "the FTC in particular should not want to take any action that would upset this agreement because it's procompetitive [to] launch at risk, and the FTC shouldn't take actions that might deter Teva from launching at risk, and making it harder to Teva to settle following a launch at risk could be a deterrent." GSK Stmt. ¶ 88-89; Pls.' Stmt. Opp. ¶ 88-89.

Teva's counsel also explained to the FTC that GSK had agreed to relinquish its right to launch an authorized generic during Teva's 180-day exclusivity period.[22] GSK Stmt. ¶ 88-89; Pls.' Stmt. Opp. ¶ 88-89.

On March 2, 2007, the FTC notified Biovail and the generic manufacturers that it would not investigate or take any further action regarding the Wellbutrin Settlement. GSK Stmt. ¶ 91-92; Pls.' Stmt. Opp. ¶ 91-92.

II. Procedural History

In May 2008, direct and indirect purchasers of Wellbutrin XL filed claims against defendants Biovail Corporation, Biovail Laboratories, Inc., and Biovail Laboratories International (together, "Biovail") and GSK, alleging that Biovail and GSK conspired to prevent generic versions of Wellbutrin XL from entering the American market by filing sham patent infringement lawsuits and a citizen petition with the Food and Drug Administration ("FDA"), and entering into agreements with generic manufacturers to settle the lawsuits. The Court certified the class of direct purchasers on August 11, 2011, and the class of indirect purchasers on August 15, 2011. The Court decertified the indirect purchaser class on June 30, 2015.

***750** On May 11, 2012 the Court granted Biovail and GSK's motions for summary judgment as to the plaintiffs' sham litigation and citizen petition claims, but deferred deciding the motions as to the settlement agreements. It was not clear until the briefing on the motions for summary judgment that the plaintiffs were arguing that the settlement agreements were an independent violation of the antitrust laws as opposed to an enhancement of the anticompetitive effects of the alleged sham litigation. The complaint had not explicitly set out this theory of liability. The legality of the settlement agreements, therefore, had not been fully briefed by the parties nor had complete discovery been taken on this topic.

On August 3, 2012, the Court approved the parties'[23] stipulated scheduling order for limited fact and expert discovery pertaining to the settlement agreements in light of the Third Circuit's decision in In re K–Dur Antitrust Litigation, 686 F.3d 197 (3d Cir.2012).

On November 7, 2012, the Court stayed the case pending the Supreme Court's decision on whether to grant certiorari in In re K–Dur Antitrust Litigation, and/or FTC v. Watson Pharmaceuticals, 677 F.3d 1298 (11th Cir.2012). On February 22, 2013, the Court continued the stay until the Supreme

Court's decision in the FTC action ("Actavis") on which the Court had granted certiorari.

The Supreme Court issued its decision in Actavis on June 17, 2013. The Supreme Court rejected both the Third Circuit's "quick look" antitrust analysis (finding reverse payment settlements presumptively unlawful) and the Eleventh Circuit's "scope of the patent" test. Rather, the Supreme Court found that reverse payment settlements are to be subject to the traditional rule of reason analysis. FTC v. Actavis, 133 S.Ct. at 2233 (2013).

In light of the Supreme Court's decision in Actavis, on January 16, 2014, the Court instructed the parties to report how they wanted to proceed. The parties continued discovery, and the motions for summary judgment were fully briefed on July 9, 2015 date. The Court held oral argument on the motions on July 29, 2015.

III. Analysis [24]

GSK has moved for summary judgment on the following grounds: (1) The Supreme Court's decision in Actavis does not apply to the Wellbutrin Settlement because the underlying patent litigation continued [25]; ***751** (2) there is no evidence in the summary judgment record that the Wellbutrin Settlement was anticompetitive under the rule of reason; (3) the plaintiffs have failed to make the requisite showings of antitrust injury and causation demanded in private antitrust litigation; (4) GSK was not a co-conspirator to any allegedly anticompetitive scheme; and (5) the settlements in the Watson and Abrika litigations cannot be a basis for the plaintiffs' recovery [26].

A. The Applicability of Actavis to the Wellbutrin Settlement

GSK has argued that the Wellbutrin Settlement, because it allowed the underlying patent litigation to continue, should not be subject to the rule of reason analysis that the Supreme Court in Actavis held should be applied to reverse payment settlements. See Oral Arg. Tr. 173-75; GSK Br. at 20-21; GSK Reply Br. at 4-5. The Court finds some support for GSK's argument.

The Supreme Court in Actavis did outline a specific type of competitive harm that justified antitrust scrutiny for reverse payment settlements: that the defendant in the patent infringement lawsuit would abandon its patent claim, eliminating the risk of patent invalidation or a finding of invalidity. F.T.C. v. Actavis, 133 S.Ct. at 2236; King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 404 (3d Cir.2015)(hereinafter "Lamictal"). This limited definition of anticompetitive harm also appears in the Supreme Court's characterization of reverse payment patent settlements as those "in which A, the plaintiff, pays money to defendant B purely so B will give up the patent fight." Id.

In finding that Actavis applies to no authorized generic agreements, the Third Circuit in Lamictal echoed Actavis and explained that "it is the prevention of that risk of competition—eliminating 'the risk of patent invalidation or a finding of non-infringement' by 'paying the challenger to stay out' of the market (for longer than the patent's strength would otherwise allow)—that 'constitutes the relevant anticompetitive harm,' which must then be analyzed under the rule of reason." Lamictal, 791 F.3d at 404 (quoting Actavis, 133 S.Ct. at 2236–37).

Anticompetitive harm as the elimination of patent litigation reflects the careful and imperfect interplay between patent law and antitrust law. Patent law grants monopolies, and patents, therefore, act as lawful restraints of trade. See Actavis, 133 S.Ct. at 2230–31 (quoting United States v. Line Material Co., 333 U.S. 287, 308, 68 S.Ct. 550, 92 L.Ed. 701 (1948))("[A] valid patent excludes all except its owner from the use of the protected process or product."). In tension with patent law's grant of exclusivity, the antitrust laws seek to prevent restraints of trade. Actavis, 133 S.Ct. at 2230–31. Patents exist as one of the exceptions to the antitrust laws' ban on restrains of trade. Lamictal, 791 F.3d at 394 ("A patent... is an exception to the general rule against monopolies...")(internal quotations omitted).

The Hatch-Waxman Act—under which the Biovail patent litigation was brought—also embodies this tension. The Act "balance[s] the goal of making available more low cost generic drugs... with the value of patent monopolies in incentivizing beneficial ***752** pharmaceutical advancement." Lamictal, 791 F.3d at 394 (quoting H.R. Rep. No. 98-857). It has a "general procompetitive thrust" and implicitly encourages challenges to patents' validity. See Id. at 2232. But at the same time, the Hatch-Waxman Act also allows for stiff penalties for the launch of "at risk" generic drugs—those marketed prior to the resolution of the patent litigation; an at risk launch may subject a generic manufacturer to steep infringement damages. This reflects a recognition that a valid and infringed patent maintains

its lawfully granted preclusive scope—a lawfully granted preclusive scope that is protected from the antitrust laws.

In Actavis, the Supreme Court explained that it is the joint objective of both patent law and antitrust law to eliminate "unwarranted patent grants" because the public should not be required to "pay tribute to would-be monopolists without need or justification." Actavis, 133 S.Ct. at 2234. Patent litigation—specifically the litigation contemplated by the Hatch-Waxman Act—serves as a check against potentially "unwarranted patent grants", and settlements that end patent litigation with a payment that causes delayed generic entry may disrupt this check. Actavis, 133 S.Ct. at 2231 ("The Paragraph IV litigation in this case put the patent's validity at issue, as well as its actual preclusive scope. The parties' settlement ended that litigation."); see also Lamictal, 791 F.3d at 405 (finding that a no authorized agreement can be anticompetitive where it induces "the generic to abandon the patent fight, [and] the chance of dissolving a questionable patent vanishes (and along with it, the prospects of a more competitive market).")

There is a critical distinction between the Wellbutrin Settlement and the settlements at issue in Actavis, Lamictal, and every other reverse payment patent settlement addressed by courts in this district post-Actavis: the generic manufacturer Anchen did not "abandon its claim" and continued to litigate the patent litigation. The Wellbutrin Settlement required the underlying patent litigation to continue, maintaining the risk of a finding of patent invalidity or non-infringement and providing for immediate generic entry upon such a finding. The settlement preserved for Anchen, therefore, the possibility—and corresponding benefits—of a victory in the underlying patent suit; the settlement preserved for Biovail the possibility—and corresponding risks—of a loss in the underlying patent lawsuit. Given this key and distinguishing provision of the settlement, the Wellbutrin Settlement does not present the same antitrust concerns that motivated the court in Actavis to subject the settlement to antitrust scrutiny.

Indeed, the Supreme Court and the Third Circuit have classified certain other types of patent lawsuit settlements as being outside the scope of antitrust scrutiny. For example, in Actavis the Supreme Court explained that parties may lawfully settle "by allowing the generic manufacturer to enter the patentee's market prior to patent expiration, without the patentee paying the challenger to stay out prior to that point.") Actavis, 133 S.Ct. at 2237. The Supreme Court did not seek to make it impossible to settle Hatch-Waxman patent infringement actions. Actavis, 133 S.Ct. at 2237; see also Lamictal, 791 F.3d at 408.

Such settlements, which are without question agreements in restraint of trade, are not subject to antitrust scrutiny because they allow the strength of the patent claims, not extra-litigation considerations, to control the outcome. At oral argument, the plaintiffs' counsel agreed that these settlements are not anticompetitive because the strength of the patent dictates the entry date. See Oral Arg. Tr. 178 ("[W]ithout money you are negotiating ***753** back and forth over the actual strength of the patent...").

Similarly, in the Wellbutrin Settlement, the patent itself remained controlling. Unlike a typical reverse payment patent settlement, in which the settlement itself keeps the patent from playing a role in the entry date, a finding of invalidity or non-infringement—a finding on the patent's strength—dictated the entry date for generic Wellbutrin XL. [27]

The Court, however, is reluctant to apply the mechanical test suggested by GSK, whereby any reverse payment that allows the underlying patent litigation to continue is automatically exempt from the antitrust laws. Such a test could foreseeably create an easily exploited antitrust loophole for reverse payment settlements. Such "formalistic approach[s]" are unhelpful in antitrust actions. See United States v. Dentsply Int'l, Inc., 399 F.3d 181, 189 (3d Cir.2005).

The Court, therefore, will analyze the Wellbutrin Settlement under the rule of reason, as the Supreme Court instructed in Actavis.

B. The Rule of Reason Analysis

GSK argues that the plaintiffs have not and cannot demonstrate that the Wellbutrin Settlement was anticompetitive under the rule of reason. The rule of reason asks three progressive questions of challenged agreements: (1) does the agreement have anticompetitive effects; (2) if so, are there procompetitive justifications for the agreement; and (3) can the plaintiffs present evidence that the challenged conduct is unnecessary to achieve those justifications. Because there is no genuine issue of material fact as to the answers to these questions, and a reasonable jury could not find the Wellbutrin Settlement to be anticompetitive under the rule of reason, the Court grants GSK's motion for summary judgment.

In Actavis, the Supreme Court instructed district courts to apply the traditional rule of reason analysis when evaluating reverse payment settlements. Actavis, 133 S.Ct. at 2237–38 ("We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation."); see also Lamictal, 791 F.3d at 403 ("courts should apply the traditional rule-of-reason analysis").

Under the traditional rule of reason analysis, the plaintiffs bear the initial burden of showing that the challenged agreement "produced adverse, anticompetitive effects within the relevant product and geographic market." Lamictal, 791 F.3d at 412 (quoting United States v. Brown Univ., 5 F.3d 658, 668–669 (3d Cir.1993). If the plaintiffs succeed in showing anticompetitive effects, the burden then shifts to the defendant to show "that the challenged conduct promotes a sufficiently pro-competitive objective." Id. The plaintiffs may then rebut the defendant's procompetitive justifications as "not reasonably necessary to achieve the stated objective." Id.

In conducting the rule of reason analysis, the Court will evaluate the Wellbutrin Settlement's reasonableness at the time it was entered into. See Polk Bros., Inc. v. Forest City Enterprises, Inc., 776 F.2d 185, 189 (7th Cir.1985); SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1207 (2d Cir.1981). The Court will also evaluate the settlement as a whole, and not in a piecemeal, provision-by-provision approach. See In re Niaspan Antitrust Litig., 42 F.Supp.3d 735, 752 (E.D.Pa.2014); see also ***754** In re Lipitor Antitrust Litig., 46 F.Supp.3d 523, 548–49 (E.D.Pa.2014). The Wellbutrin Settlement was negotiated as a whole, agreed to as a whole, and went into effect as a whole, so failing to evaluate the agreement as a whole would overlook context essential to determining any possible anticompetitive effects.

To survive summary judgment, the plaintiffs must present a "genuinely disputed issue of material fact" as to the elements of the rule of reason analysis; only then will the case go to a jury. In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 316 & n. 12 (3d Cir.2010); see also In re Chocolate Confectionary Antitrust Litig., —— F.3d ——, ——, 2015 WL 5332604 at *6 (3d Cir. Sept. 15, 2015)("[T]he summary judgment standard in antitrust cases is generally no different from the standard in other cases."); Lamictal, 791 F.3d at 413 n. 38 (explaining that "nothing in this opinion precludes a defendant from prevailing on a...motion for summary judgment").

1. Anticompetitive Effects

The plaintiffs bear the initial burden under the rule of reason to demonstrate that the agreement had anticompetitive effects. Nw. Wholesale Stationers, Inc. v. Pacific Stationery and Printing, Co., 472 U.S. 284, 297 n. 9, 105 S.Ct. 2613, 86 L.Ed.2d 202 (1985); United States v. Brown Univ. in Providence in State of R.I., 5 F.3d 658, 668 n. 8 (3d Cir.1993). They have failed to meet that burden. [28]

The plaintiffs, as discussed in detail above, cannot establish that the Wellbutrin Settlement presented the type of anticompetitive harm contemplated by Actavis and Lamictal because the settlement did not induce the generic manufacturer "to quit its patent challenge" and thus did not eliminate the "risk of patent invalidation or a finding of non-infringement" by the court. [29] Lamictal, 791 F.3d at 411. In contrast, the Wellbutrin Settlement specifically contemplated that the generic manufacturer would continue its patent challenge and allowed the generic to enter immediately upon a finding of patent invalidity, maintaining the risk of patent invalidation or a finding of non-infringement even after the settlement. [30] This was not the type of settlement or anticompetitive harm that faced the Supreme Court in Actavis.

Because the plaintiffs cannot allege the anticompetitive harm contemplated by Actavis or addressed in Lamictal, they necessarily rely on alternate theories to satisfy their burden under the rule of reason: (1) that a showing of GSK's market power in the bupropion hydrochloride market is enough to satisfy their initial burden under the rule of reason; and (2) that the Wellbutrin Settlement delayed the launch of 150mg generic Wellbutrin XL.

a. Market Power

The plaintiffs have suggested that a showing of GSK's market power over the bupropion hydrochloride market satisfies ***755** their initial burden under the rule of reason. In the context of reverse payment patent settlement lawsuits, however, the Court finds that market power alone cannot be sufficient to demonstrate anticompetitive effects under the rule of reason.

Although the Lamictal court, in quoting Brown University, acknowledged that "courts typically allow proof of market power instead" of proof of actual anticompetitive effects, the court did not find that market power could supplant proof of anticompetitive effects in reverse payment patent settlement lawsuits. Lamictal, 791 F.3d at 412. In fact, the court continued to explain that "to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition." By continuing its explanation, the Lamictal court was clear that it was not enough for the plaintiffs simply to prove market power. Id.; see also In re Nexium (Esomeprazole) Antitrust Litig., 968 F.Supp.2d 367, 389–90 (D.Mass.2013)(recognizing that plaintiffs must demonstrate both market power and anticompetitive effects).

In explaining the application of the rule of reason to reverse payment patent settlements, the Supreme Court distinguished a showing of market power from the necessary showing of the anticompetitive harm of such payments. Actavis, 133 S.Ct. at 2236 ("[W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm into practice."). Allowing market power alone to satisfy the plaintiffs' burden of showing actual anticompetitive effects in reverse payment patent lawsuits is likely to treat the settlements as presumptively unlawful because, while a patent does not create a presumption of market power, Illinois Tool Works Inc. v. Independent Ink, Inc., 547 U.S. 28, 31, 126 S.Ct. 1281, 164 L.Ed.2d 26 (2006), by their nature pharmaceutical patents often carry with them market power, Actavis, 133 S.Ct. at 2236. Actavis rejected a framework under which reverse payment settlements were presumptively unlawful.

To allow a showing of market power to satisfy the plaintiffs' burden under the rule of reason would be in tension with the holdings of Actavis and Lamictal. The plaintiffs, therefore, must show actual anticompetitive effects of the Wellbutrin Settlement.

b. Delayed Wellbutrin XL Entry

In attempting to demonstrate the anticompetitive effects of the Wellbutrin Settlement in the form of a delayed entry, the plaintiffs first argue that they must show only a "large payment" (in the form of a no authorized generic agreement) and a "delay" of generic entry. This argument appears to be advocating that the Court use a "quick look" analysis [31] whereby every reverse payment settlement presumptively has anticompetitive effects because there is a payment and a subsequent delay of generic entry. [32] Although "pay for delay" ***756** may be a useful shorthand for discussing reverse payment settlements, it does not capture the entirety of the antitrust analysis. In fact, such an analysis was explicitly rejected by the Supreme Court in Actavis. Actavis, 133 S.Ct. at 2236–37 ("The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful... We decline to do so."). Even if a reverse payment settlement agreement does end the underlying patent litigation, anticompetitive effects are not presumed: "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." Lamictal, 791 F.3d at 412 (quoting Actavis, 133 S.Ct. at 2237).

The plaintiffs also attempt to show anticompetitive effects by arguing that GSK viewed the no authorized generic promise as being made for delayed generic entry; to support this, the plaintiffs rely on both testimony by GSK officials [33] and internal GSK documents [34]. At most, the evidence shows recognition on the part of GSK that generic Wellbutrin XL could not enter the market until either Anchen/Teva succeeded on appeal or until the trigger date of May 30, 2008, whichever is earlier, and that a no authorized generic promise was made. The plaintiffs therefore fail to establish that the no authorized generic agreement caused the delayed entry. Even if the evidence showed a contemplated connection, however, that may not be enough to satisfy the plaintiffs' initial burden under the rule of reason where, as here, the underlying patent litigation continued after the settlement was reached and the question of patent validity remained with the court. [35]

It is in keeping with the traditional rule of reason analysis to require the plaintiffs to show that the Wellbutrin Settlement actually resulted in the delayed entry of Wellbutrin XL—that absent the Wellbutrin Settlement, generic competition would have occurred earlier. The plaintiffs' ***757** own expert Dr. Leitzinger recognized that "[t]he operative question is the manner in which the agreement—inclusive of the reverse payment—altered the date at which generic entry otherwise would have occurred." Leitzinger Decl. (Oct. 6, 2014). [36] The plaintiffs' evidence, therefore, presents two but-for scenarios that could allow them to show the anticompetitive effects

of the Wellbutrin Settlement: (1) that a settlement allowing earlier entry would have been reached absent a no authorized generic agreement; or (2) that continued litigation would have resulted in earlier entry. The plaintiffs have failed to offer any proof for either of these but-for scenarios.

i. Alternative Settlement Scenario [37]

There are no facts in the summary judgment record to support a contention that, absent the no authorized generic agreement, an alternate settlement would have been reached.

The summary judgment record, in fact, shows the opposite: Teva expressly and unwaveringly refused to settle the Biovail litigation unless the settlement contained a no authorized generic agreement. Teva had demanded a no authorized generic promise prior to GSK's involvement in the settlement process; prior to GSK's involvement, the parties had tried and failed to negotiate a settlement agreement without a no authorized generic agreement. It was Teva's insistence on the no authorized generic promise that made it necessary for Judge Brody to require GSK's involvement in the settlement process, and Teva continued to demand a no authorized generic promise after GSK was instructed by Judge Brody to participate in the settlement process. As further evidence of Teva's insistence, every draft of the Wellbutrin Settlement included a no authorized generic agreement. Brannon Dep. Tr. 129:14-130:5 ("Teva...was very adamant that certain issues were deal breakers for them, and they required GSK to waive certain rights if there was going to be any settlement at all."); Bauer Dep. Tr. 57:8-13; GSK Exs. 10, 63.

The plaintiffs' expert Dr. Leitzinger offers no testimony in support of a contention that an alternate settlement would have been reached. Dr. Leitzinger states instead that "one can fairly infer the presence of delay simply from the fact of a reverse payment that is not otherwise justified," and Dr. Leitzinger did not "[try] to answer the question of what specifically ***758** some alternative form of settlement would have looked like." Leitzinger Decl. ¶ 32; Leitzinger Dep. Tr. 46:22-24.

ii. Continued Litigation Scenario

Alternatively, the plaintiffs argue that had the Wellbutrin Settlement not been reached, the litigation would have continued, Teva would have launched generic Wellbutrin XL "at risk" of the pending litigation, and GSK would have launched [38] its own authorized generic Wellbutrin XL product.

As discussed in detail in Section D, this argument for anticompetitive effects fails because the summary judgment record does not contain evidence that Anchen would have succeeded in both the Biovail appeal and the Andrx litigation.

Although he Court is not convinced that the plaintiffs have met their preliminary burden of demonstrating anticompetitive effects of the Wellbutrin Settlement, the Court, nevertheless, will continue the rule of reason analysis and evaluate the procompetitive justifications for the Wellbutrin Settlement.

2. The Wellbutrin Settlement's Procompetitive Justifications

If plaintiffs meet their initial burden of presenting sufficient evidence of anticompetitive effects, the defendant must then show that the "challenged conduct promotes a sufficiently procompetitive objective." U.S. v. Brown University in Providence in State of R.I., 5 F.3d 658, 669 (3d Cir.1993); see also Race Tires, Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 74–75 (3d Cir.2010). Procompetitive benefits are those that "enhance consumer welfare and competition in the marketplace" and are "consistent with the procompetitive aspirations of antitrust law." Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 309 (3d Cir.2007). Summary judgment is appropriate if there is no dispute of material fact and no reasonable jury could find that the anticompetitive effects outweigh the proffered procompetitive justifications.

In the context of reverse payment settlements, the Supreme Court in Actavis found that the settlements would only sometimes "prove unjustified" and could be justified as a reflection of litigation expenses, the cost of services performed by the generic manufacturers, or other justifications. Actavis, 133 S.Ct. at 2235–36 ("[O]ffsetting or redeeming virtues are sometimes present."); see also In re Cipro Cases I & II, 61 Cal.4th 116, 158, 187 Cal.Rptr.3d 632, 348 P.3d 845 (2015)(recognizing that procompetitive justifications must be considered).

GSK has presented the following procompetitive justifications for the Wellbutrin Settlement: (1) the Andrx License that allowed Anchen/Teva to enter the generic Wellbutrin Market without the risk of losing the Andrx case;

(2) a provision obligating Biovail to supply Teva with generic Wellbutrin if Anchen faced manufacturing or regulatory hurdles; and (3) a provision guaranteeing Anchen/Teva immediate entry if Anchen prevailed in the Biovail appeal, or no later than May 30, 2008 even if Biovail prevailed. There are no genuine issues of material fact as to the procompetitive nature of GSK's justifications; both the Andrx sublicenses and the supply provision ***759** offered the generic manufacturers —and thus the consumers—something they could not have received through successful litigation alone. Even if the plaintiffs had demonstrated anticompetitive effects of the Wellbutrin Settlement, therefore, GSK has successfully presented sufficiently procompetitive justifications. The plaintiffs have not presented an actual factual dispute as to GSK's procompetitive justifications.

a. The Andrx Sublicense

The Wellbutrin Settlement included a provision through which GSK—through Biovail—sublicensed Andrx's product to Anchen/Teva, eliminating an independent and substantial hurdle to generic entry. Andrx had sought injunctive relief to keep Anchen/Teva off the market; Andrx's patent was set to expire in 2022. At the time of the Wellbutrin Settlement, GSK entered into a settlement agreement with Andrx, whereby GSK paid Andrx $35 million in satisfaction of Andrx's infringement claims for sales prior to February 1, 2007, and a 3.5% royalty of its net sales for sales following February 1, 2007. GSK Ex. 5. The settlement agreement also allowed GSK to sublicense its rights to Biovail, which could in turn sublicense those rights to the generic manufacturers. Anchen/Teva received that sublicense as a provision of the Wellbutrin Settlement.

Anchen had been severely limited in its defense of the Andrx lawsuit in which Andrx had sought damages and injunctive relief to prevent the sale of generic Wellbutrin XL; Andrx's lawsuit against Anchen was not brought under the Hatch-Waxman Act. Anchen's CEO at the time of the lawsuit was the inventor of the Andrx patent, and therefore the doctrine of inventor estoppel prevented Anchen from arguing that the Andrx patent was invalid (GSK had asserted patent invalidity in defense of Andrx's lawsuit). Teva, leading the settlement negotiations for the generics, expressed concern about this limitation. Holding Dep. Tr. 64:18-65:20.

The summary judgment record demonstrates that Teva demanded that the Wellbutrin Settlement to provide a sublicense to the Andrx patents. Contemporaneous documents show that Teva wanted the "full freedom to operate" without the risk of either the Biovail or Andrx patent infringement claim and anticipated that GSK's negotiations with Andrx would include address generic license for Anchen/Teva. GSK Ex. 64. The Wellbutrin Settlement guaranteed Teva that freedom, and eliminated the possibility that Andrx could prevent generic Wellbutrin XL from being marketed for the 15 years remaining on its patent. Absent a license for the Andrx patent or success in the underlying litigation, it would have been impossible for Anchen/Teva lawfully to market generic Wellbutrin XL.

b. The Biovail/Teva Supply Provision

The Wellbutrin Settlement also included a supply provision that required Biovail to supply Teva with Wellbutrin XL if (1) Teva faced limited supply from Anchen or (2) the FDA ruled on Biovail's citizen petition in a way that made generic Wellbutrin XL non-compliant. Biovail was obligated to provide up to 75 million pills if Anchen faced supply issues, and an unlimited amount of pills if the outcome of the citizen petition made generic Wellbutrin XL non-compliant. GSK Ex. 6.

The parties to the Wellbutrin Settlement extensively negotiated the settlements' supply provisions. Nine versions of the supply terms were exchanged between the December 16, 2006 draft and the final February 9, 2007 Wellbutrin Settlement. See GSK Exs. 6, 10-17.

The summary judgment record is clear that Teva was concerned about its ability to market generic Wellbutrin XL on the trigger date, and was therefore highly motivated ***760** to negotiate a robust supply option. In an email from Teva's General Counsel to counsel for Biovail and GSK, Teva's counsel stated that "[t]he supply commitment can't be more watered down and useless—this wasn't the intent." Pls. Ex. 886 ("We [Teva] need to be able to sell on the trigger date. This requires reasonable preparations."; Brannon Dep. Tr. 163:12-164:3; Holding Dep. Tr. 96:24-97:3; Bauer Dep. Tr. 112:6-13 ("there's concern if there was an earlier trigger date that Anchen might not be able to have a continuous supply without a backorder situation"); GSK Ex. 67 (A February 2007 email from Teva explaining that Teva was concerned about supply if a launch would occur in October 2007).

Supply contracts can assure steady supply, limit risk, and allow for long-term planning on the part of the recipient. Standard Oil Co. v. United States, 337 U.S. 293, 306, 69 S.Ct. 1051, 93 L.Ed. 1371 (1949). In this case, the The Wellbutrin Settlement supply provision "ensure[d] that the generic will be able to be on the market if there's a regulatory reason why it otherwise could not be." Holding Dep. Tr. 52:7-16. The provision was designed to achieve the seamless facilitation of a risk-free generic Wellbutrin XL launch by ensuring consistent supply of product to Teva, and thus to consumers.

c. Continued Litigation

Finally, the Wellbutrin Settlement preserved for consumers the benefits of Anchen/Teva's immediate entry should Anchen prevail in the Biovail appeal. Under the Wellbutrin Settlement, once Anchen succeeded on appeal, Anchen/Teva were in a position to lawfully enter the market with generic Wellbutrin XL, not at risk of infringing the Biovail patent. The Wellbutrin Settlement also allowed Anchen/Teva to market generic Wellbutrin XL on May 30, 2008 at the latest—ten years prior to patent expiration—even if Biovail prevailed on appeal. Finally, the Wellbutrin Settlement eliminated the liability Anchen faced for its at risk launch of 300mg generic Wellbutrin XL. GSK Exs. 6, 46; Holding Dep. Tr. 55:16-20.

3. Balancing Anticompetitive Elements with the Procompetitive Benefits

An allegedly anticompetitive restraint survives a rule of reason analysis if it achieves legitimate, procompetitive justifications and is reasonably necessary to achieve those justifications. Brown Univ., 5 F.3d at 678–79. "To determine if a restraint is reasonably necessary, courts must examine first whether the restrain furthers the legitimate objectives, and then whether comparable benefits could be achieved through a substantially less restrictive alternative." Id. To survive summary judgment, the plaintiffs have the burden of presenting evidence that raises a material dispute of fact regarding the procompetitive justifications offered by the defendants. Id. The plaintiffs have not met that burden.

The plaintiffs have not presented evidence to challenge GSK's procompetitive justifications on the grounds that the allegedly anticompetitive conduct was unnecessary to achieve the justifications. In fact, as discussed above, there would have been no settlement agreement—and thus no supply provision or sublicense—had GSK not agreed to abstain from marketing an authorized generic product.

Rather, the plaintiffs challenge GSK's procompetitive justifications on the grounds that the justifications themselves are "unnecessary", "illusory", and "pretextual".

The summary judgment record, however, does not contain any evidence that would allow a reasonable jury to find that GSK's procompetitive justifications were "unnecessary", "illusory", or "pretextual".

First, the plaintiffs argue that Anchen did not need GSK's "help" to negotiate the ***761** Andrx settlement because the parties had been engaging in bilateral settlement discussions. Although it is undisputed that Anchen and Andrx were directly communicating regarding the Andrx litigation, it is further undisputed that no bilateral settlement agreement was ever reached. The plaintiffs' contention that bilateral discussions were taking place mere weeks before the final Wellbutrin Settlement was reached misrepresents the documentary evidence: in fact, Teva and Anchen were having discussions with Andrx subject to the Wellbutrin Settlement, not apart from it. Pls. Ex. 864; Bauer Dep. Tr. 233:11-15; 240:7-12.

The plaintiffs challenge the Teva supply provision on similar grounds. It is undisputed, however, that Teva aggressively negotiated for the provision and that the provision remedied the possible supply hurdles perceived by Teva. Further, although the plaintiffs focus on the fact that no final supply agreement was actually reached, there is a clear explanation: neither of the supply-triggering events (a successful citizen's petition or an appellate victory) ever occurred. See Bauer Dep. Tr. 100:3-7 ("I think, as a business matter, it would make sense that we would...want to have that kind of backup supply option under these circumstances.").

4. Submission of the Wellbutrin Settlement to the FTC

The parties to the Wellbutrin Settlement presented all elements of the Wellbutrin Settlement—including the allegedly anticompetitive elements and the procompetitive justifications—to the FTC. The summary judgement record demonstrates that the Wellbutrin Settlement provided for FTC review beyond what is required by the MMA. The Wellbutrin Settlement required the parties to present the entirety of the settlement to the FTC on an abbreviated time frame, resolve

any questions or concerns raised by the FTC in response to the settlement, and terminate the settlement in the event the FTC's questions or concerns could not be addressed. A note of concern from the agency was sufficient to alter or terminate the settlement; no formal agency action was necessary.

The parties presented the Wellbutrin Settlement to the following individuals at the FTC: Markus Meier, the head of the FTC's Health Care Division; Bradley Albert, the Deputy Assistant Director of the FTC's Health Care Division; and FTC staffer Meredyth Smith Andrus. After meeting with the parties and reviewing the settlement, the FTC raised no concerns regarding the Wellbutrin Settlement. [39]

GSK argues that the FTC's decision not to challenge the Wellbutrin Settlement underscores its procompetitive character. GSK urges the court to follow the decision of another district court that held that any "antitrust intent" on the part of the defendants was negated by the defendants' submissions to the FTC beyond what was required by the MMA and the FTC's subsequent decision not to pursue any action. In re Effexor Antitrust Litig., 2014 WL 4988410 at *24 (D.N.J. October 6, 2014). The Court does not find the FTC's decision not to challenge the Wellbutrin Settlement determinative on any issue presented in the motions, but the provisions for enhanced FTC review do tend to negate any anticompetitive aim of the parties, in particular GSK. [40]

***762** The provisions for enhanced FTC review may also be described as procompetitive, at least in an indirect way. If the FTC objected to the settlement, the parties agreed that they would either resolve the objection or have the right to terminate the entire settlement. The FTC was given, in effect, veto power over the Wellbutrin Settlement. The FTC, therefore, did not have to use their limited resources to file a lawsuit to force changes to the agreement or even abrogation of it; the FTC only had to raise concerns to have the agreement changed in a way that would be more beneficial to consumers.

C. Antitrust Injury/Causation

GSK argues that the plaintiffs cannot establish antitrust injury or causation, two essential elements in any private antitrust action. GSK's argument takes two forms: (1) the plaintiffs cannot show antitrust injury or causation because they cannot show that it was the Wellbutrin Settlement, rather than the underlying patent(s), that prevented generic entry; and (2) in the alternative, the plaintiffs cannot establish causation because they cannot show that Anchen/Teva could have and would have entered at risk.

Although the plaintiffs concede that they must show antitrust injury and causation, they argue that both elements are made out by their showing of a large payment and a delay. In essence, the plaintiffs argue that once they have shown a large payment and a delay, they have established not only anticompetitive conduct but also antitrust injury or causation. The Court concludes that the principle propounded by the plaintiffs would not only eviscerate the rule of reason analysis, as discussed above, but also ignores the long-standing and strict principles of antitrust injury and causation.

To succeed in an action under Section 4 of the Clayton Act, private plaintiffs must show that they suffered an antitrust injury and that the defendant's allegedly anticompetitive conduct was the actual and proximate cause of that antitrust injury. 15 U.S.C. § 15. In many cases, and in this case, the questions of antitrust injury and causation are closely linked and most effectively analyzed together. [41] See, e.g., West Penn Power Co., 147 F.3d at 266.

Antitrust injury is "an injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful." [42] ***763** Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc., 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977). To be an antitrust injury, the injury must "reflect the anticompetitive effect either of the violation or of the anticompetitive acts made possible by the violation" and represent "the type of loss that claimed violations...would be likely to cause." Id.; see also Race Tires Am. Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 76 (3d Cir.2010); City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 266 (3d Cir.1998).

Antitrust injury cannot be presumed simply because there is an agreement that results in harm. J. Truett Payne, Inc. v. Chrysler Motors Corp., 451 U.S. 557, 562, 101 S.Ct. 1923, 68 L.Ed.2d 442 (1981); see also City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 266. The ban on presumption of antitrust injury is supported by the Clayton Act's strict causation requirement.

To establish causation, the Clayton Act requires antitrust plaintiffs to demonstrate that their injuries were caused "by reason of" allegedly anticompetitive conduct. 15 U.S.C. § 15(a). The "by reason of" language requires both a showing that defendant's actions were the but-for and the proximate

cause of the injury. Assoc. Gen. Contractors of Calif. v. California State Council of Carpenters, 459 U.S. 519, 103 S.Ct. 897, 905, 74 L.Ed.2d 723. Private plaintiffs bear the burden of establishing causation. See Out Front Prods., Inc., v. Magid, 748 F.2d 166, 169 (3d Cir.1984)(citing Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 114 n. 9, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969)).

Given the Clayton Act's "by reason of" language, an independent regulatory scheme can cut off the necessary chain of causation.[43] As the Third Circuit explained in City of Pittsburgh v. West Penn Power Co.:

> the interposition of the regulatory scheme and actions of the parties—both defendants and plaintiff—interferes with the chain of causation. The statutory scheme precluded competition without the requisite regulatory permission. As Professors Areeda & Hovencamp describe, 'a plaintiff cannot be injured in fact by private conduct excluding him from the market when a statute prevents him from entering the market in any event.'

West Penn Power Co., 147 F.3d at 267–68 (emphasis added); see also In re Nexium (Esomeprazole Antitrust Litig., 42 F.Supp.3d 231, 265–75 (D.Mass.2014)(finding the chain of causation broken because there was no evidence that the generic manufacturer could have received the necessary regulatory approvals).

Other circuits have likewise found that an independent regulatory limitation can cut off the chain of causation under the Clayton Act. In In re Canadian Import Antitrust Litigation, the plaintiffs claimed that the defendants unlawfully conspired to prevent the import of ***764** Canadian prescription drugs for personal use. 470 F.3d 785 (8th Cir.2006). The Eighth Circuit found that the plaintiffs could not establish antitrust injury because the importation of drugs from Canada was banned under federal law, and therefore the absence of Canadian drugs in the American market was caused by "the federal statutory and regulatory scheme adopted by the United States government, not by the conduct of the defendants." Id. at 791. Therefore, "the alleged conduct of the defendants did not cause an injury of the type that the antitrust laws were designed to remedy." Id.

Similarly, in RSA Media, Inc. v. AK Media Group, the First Circuit did not allow plaintiffs to recover for the defendants' allegedly anticompetitive refusal to sell the plaintiffs' billboard access, because the plaintiffs' desired entrance into the billboard market was blocked by a Massachusetts regulatory scheme that operated independent of the the defendants' conduct. 260 F.3d 10 (1st Cir.2001). The court found that because market exclusion was a byproduct of a government scheme, the plaintiffs could not demonstrate the "by reason of" causation necessary under the Clayton Act. Id. at 14–15.

In discussing its application of the rule of reason to reverse payment settlements, the Supreme Court in Actavis explained that it is "normally not necessary to litigate patent validity to answer the antitrust question" because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." Actavis, 133 S.Ct. at 2236. Actavis, however, was brought by the FTC. The FTC faces a different standard of causation in bringing agency antitrust actions such as Actavis: the FTC must establish only that the defendant's action is "likely to cause injury." 15 U.S.C. § 45.[44] Because the FTC Act's causation requirement is broader and more relaxed than the Clayton Act's, no showing of proximate cause is required. Compare 15 U.S.C. 45(n) with 15 U.S.C. § 15(a). The hurdle, therefore, that independent regulation poses for causation under the Clayton Act is not necessarily present in FTC Actions.

The Supreme Court's language in Actavis directly tracks the FTC Act's "likely to" causation standard. Because the FTC must show only that the agreement at issue was "likely to" cause harm, and the payment itself "normally suggest[s]" a low likelihood of success on the patent suit, it is understandable that an analysis of patent validity may normally be unnecessary in actions brought under the FTC Act.

But the Clayton Act does demand such an analysis, and nothing in Actavis altered the Clayton Act's causation requirement. Unlike the FTC Act, the Clayton Act's "by reason of" causation requirement cannot be satisfied by using the size of the payment as a proxy for patent strength and the success of the underlying patent litigation. The "heart of a [patent monopoly] is the right to invoke the state's power" to prevent others from marketing the patented product. Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 135, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969). The existence of a valid and uninfringed patent would interfere with the plaintiffs' chain of causation: a valid patent independently "preclude[s] competition" apart from any agreement and an "at risk" launch is unlawful absent a later finding of patent invalidity or non-infringement.[45] See ***765** West Penn Power Co.,

147 F.3d at 269. Where a regulation—such as patent law—precludes competition, that regulation cuts off the chain of causation. In other words, if an agreement only replicates the effect of the underlying patent litigation, any exclusion resulting from that agreement must be caused by the underling patent. See id.

To succeed under the plaintiffs' theory of anticompetitive harm—that the Wellbutrin Settlement prevented an at risk launch of generic Wellbutrin XL—the plaintiffs must show first that it was the Wellbutrin Settlement, and not the underlying patents, that prevented market entry of generic Wellbutrin XL, and second, that Anchen/Teva had the ability and the intent to launch at risk.

1. Success on the Underlying Patent Lawsuits [46]

Anchen/Teva had not one but two patent litigations to overcome in order lawfully to launch Wellbutrin XL: The Biovail Litigation and the Andrx Litigation. Failure in either action would have served as an independent bar to the marketing of generic Wellbutrin XL. The Court cannot conclude that no reasonable juror could find that Anchen would have prevailed in the Biovail litigation, but the Court does conclude that no reasonable juror could find that Anchen would have succeeded in the Andrx patent litigation.

GSK has presented the expert opinion of Dr. Martin J. Adelman on both the Biovail and the Andrx litigations. The plaintiffs have filed a Daubert motion to exclude the testimony of GSK's patent litigation expert Dr. Adelman. In their motion, the plaintiffs have taken the position that Dr. Adelman is not qualified to offer expert opinion and has used unreliable methodologies.

Dr. Adelman, however, is a qualified expert offering appropriate expert testimony. The Court, therefore, denies the plaintiffs Daubert motion.

Federal Rule of Evidence 702 allow a "witness who is qualified as an expert by knowledge, skill, experience, training, or education" to offer opinion testimony. Fed. R. Evid. 702. To offer opinion testimony, the expert must offer "scientific, technical, or other specialized knowledge" to "help the trier of fact understand the evidence or to determine a fact in issue." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589–91, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Courts in this Circuit must evaluate the expert's qualifications, methodologies, and "fit" of the proposed testimony to the case to determine admissibility. ***766** In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741–43 (3d Cir.1994).

In his Second Expert Report (Dr. Adelman's first report addressed whether Biovail's patent claims against Anchen were shams), Dr. Adelman opines that (1) Biovail had a greater than 50 percent chance of prevailing in the Biovail litigation and (2) Andrx had an 80 percent chance of prevailing in its infringement suits against GSK and Anchen. Adelman Second Rep. ¶¶ 16, 18, 22, 64.

Dr. Adelman is a patent law professor who has taught at George Washington University Law School, University of Michigan Law School, and Wayne State University Law School. In forming his opinions, Adelman relied on the ANDA interpretations made by FDA experts; the plaintiffs did the same in addressing the since-dismissed sham litigation claims. Dr. Adelman also relied on the opinion of GSK's chemistry expert, Dr. Burgess. Dr. Adelman, an expert in patent litigation, appropriately relies on the conclusions of other experts in reaching his opinion, and is qualified to give that opinion. Adelman Second Rep. ¶¶ 1-3, 14, 44-47.

The Court, therefore, will consider Dr. Adelman's opinion in evaluating both the Biovail and Andrx litigations. [47]

a. Biovail Litigation

Biovail appealed the district court's grant of summary judgment to Anchen in the Biovail litigation on two grounds: (1) the district court's claim construction regarding the claim "free of stabilizer" and (2) the district court's summary judgment decision regarding the ANDA indicating that "there was no HCl in the final formulation." Had Biovail prevailed on either argument, the case would have been remanded to the district court for reconsideration.

GSK has offered the expert opinion of Dr. Adelman that: (1) "there is a strong likelihood that Biovail would have prevailed" on either—or both—claim construction or infringement and (2) had the "Federal Circuit reversed on one or both issues, it almost certainly would have remanded the case to the district court for further proceedings consistent with its opinion." Given those considerations, Adelman concluded that Biovail had a more-than-50 percent chance of success on appeal. Adelman Second Rep. ¶¶ 22-24, 123-25, 127.

On appeal of the claim construction order, Biovail had argued that "free of stabilizer" may have meant free of any functionally stabilizing amount, rather than any stabilizing amount. The district court in the Biovail litigation had found otherwise in its grant of summary judgment. Other district courts evaluating the same patent and ANDA and relying on each other's reasoning had found similarly at the summary judgment stage. Biovail Labs. Int'l SRL v. Impax Labs., Inc., 433 F. Supp. 2d 501, 505 (E.D.Pa.2006); Biovail Labs. Int'l SRL v. Abrika, LLP, No., 04–61704, 2006 WL 6111777 at *13 (S.D.Fla. Aug. 24, 2006).

The plaintiffs have not offered their own expert to rebut Dr. Adelman's testimony. Instead, the plaintiffs rely on the grant of summary judgment by the district court, and their own counsel's analysis of Biovail's chances of success on appeal. See Oral Arg. Tr. 74-76. The latter undoubtedly would not be admissible at trial. Having said that, and acknowledging that GSK did an excellent job of making the case for ***767** Biovail prevailing in the litigation, the Court cannot conclude that no reasonable juror could find that Anchen would have succeeded in the Biovail litigation. The grant of summary judgment by the district court would be powerful evidence to overcome and Dr. Adelman would have no doubt been vigorously cross examined by plaintiffs' counsel.

b. Andrx Litigation

There is no question of fact, however, as to Anchen's likelihood of success in the Andrx Litigation: The summary judgment record contains no evidence that Anchen would have succeeded in defending Andrx's patent infringement claim, and the plaintiffs do not even argue that the generic manufacturers could have succeeded in the Andrx litigation. [48]

Upon a review of the briefs, pleadings, ANDA, and underlying patent at issue in the Andrx litigation, GSK's expert Dr. Adelman concluded that Andrx had an 80 percent chance of prevailing on the patent litigation; Anchen's success was unlikely. There is no dispute of fact as to Dr. Adelman's conclusions, and no countervailing facts in the summary judgment record. No reasonable juror could find, based on this record, that Anchen could have succeeded in the Andrx litigation.

Further, in the Andrx Litigation, Anchen would have been prevented from arguing that the patent is invalid or unenforceable under the doctrine of inventor estoppel, which prevents an inventor of a patent from later arguing that the same patent is invalid or unenforceable. Shamrock Tech., Inc. v. Med. Sterilization, Inc., 903 F.2d 789, 793 (Fed.Cir.1990). In this case, Anchen's founder and Chief Executive Offer invented and then assigned to Andrx the rights to the '708 patent, the patent at issue in the Andrx suit. There is no dispute of material fact, therefore, that Andrx would have succeeded in the underlying patent claim.

Because there is no question of material fact as to whether Andrx would have succeeded in its underlying patent claim, the Andrx patent served as an independent regulatory bar to Anchen's launch; an at risk launch would have been unlawful and subject to damages and injunctive relief. It was the patent itself, therefore, and not the Wellbutrin Settlement, that caused generic Wellbutrin XL's lack of market presence.

2. Anchen/Teva's Possible At Risk Launch

To succeed on their theory that Anchen/Teva would have launched at risk absent the Wellbutrin Settlement, the plaintiffs must establish that Anchen/Teva could have and would have done so. GSK has argued that (1) FDA regulations barred Anchen/Teva's planned March 2007 at risk launch; and (2) there is no evidence in the summary judgment record that Anchen/Teva contemplated a June 2007 at risk launch given the regulatory hurdles faced in May. GSK is correct that Anchen/Teva was prevented under FDA regulations from a launch before June 2007; but there is a question of fact as to whether Anchen/Teva would have launched at risk following June 2007.

The ANDA submitted by Anchen for production of its generic Wellbutrin XL product listed only the Goodyear Facility as a manufacturing site, although Anchen ultimately produced its generic Wellbutrin XL at its Jeronimo Facility. The FDA first learned of the production site change in January 2007 during its inspection. On ***768** May 29, 2007, Anchen received the report from FDA's inspection: the report stated that the Jeronimo Facility required final approval. The FDA allowed Anchen to get its approval by submitting a supplement to its ANDA; the FDA accepted Anchen's ANDA supplement on June 11, 2007, making production permitted at the Jeronimo Facility on June 12, 2007. Under FDA regulations, Anchen

was not permitted to launch its generic Wellbutrin XL before this date. 21 C.F.R. § 314.70.[49]

Similar to the regulatory ban in West Penn Power Co., the FDA's regulations "precluded competition without the requisite regulatory permission." West Penn Power Co., 147 F.3d at 268. It was the FDA regulations, not the Wellbutrin Settlement, that delayed possible generic entry until June 2007; the FDA's independent action cuts of the plaintiffs' requisite chain of causation. Accordingly, even assuming that the plaintiffs could have shown success on the underlying patent lawsuits, they could not recover for damages prior to June 2007.

There is a question of fact, however, as to whether Anchen/Teva would have launched an authorized generic in June 2007. The plaintiffs have pointed to evidence in the summary judgment record that in late 2006 and early 2007 Anchen/Teva had planned to launch generic Wellbutrin XL "at risk" of the ongoing patent litigation. Internal emails between Anchen and Teva addressed the possibility of an at risk launch, and meeting minutes and presentations anticipated a "1Q07" launch for generic Wellbutrin XL. See Pls. Exs. 772, 813, 846, 922, 899, 915, and 770.

The plaintiffs have also relied on the following circumstances to support their contention that Anchen/Teva would have launched at risk following June 2007: (1) Teva and Impax launched 300mg Wellbutrin XL at risk; (2) Teva and Anchen had the financial incentive to launch at risk "as soon as possible" to take advantage of its 180-day exclusivity period; (3) Anchen had manufactured product for an at risk launch; and (4) Teva frequently launches its products at risk. Finally, the Distribution and Supply Agreement between Teva and Anchen required Teva to launch at risk absent an "adverse occurrence." Pls Ex. 844; Bauer Dep. Tr. 209:7-210:6.

The plaintiffs, however, have not presented any evidence through documents or testimony that an at risk launch would have occurred in June 2007 in view of the regulatory hurdles faced by Anchen/Teva.[50] Rather, the plaintiffs take the position that nothing had changed "in the 'but-for' world between February and June of 2007." Pls. Opp'n at 18.

GSK is correct that the summary judgment record does not establish a certainty of a post-June 2007 at risk launch. Notably, the circumstances surrounding Teva/Impax's launch of 300mg generic Wellbutrin XL were different than those of Anchen/Teva's possible 150mg launch. Impax did not face the regulatory and production hurdles faced by Anchen, and Impax did not face a patent infringement suit by Andrx. The plaintiffs have not offered support for their contention that it was "commonplace" for Teva to launch at risk.

The Court cannot conclude, however, that no reasonable juror could find that ***769** Anchen would have launched at risk after June 2007 given the Anchen/Teva documents that explicitly contemplate an at risk launch. Although the Anchen/Teva documents discussing a planned at risk launch may have been prepared prior to Anchen's regulatory hurdles, those regulatory hurdles were resoved in June 2007 and a reasonable juror could conclude that the earlier analysis as to at risk entry would apply after June 2007.

Finally, GSK does not address Anchen and Teva's agreement to launch at risk. The existence of such an agreement may allow a reasonable jury to find that Anchen/Teva would have launched at risk after June 2007.

D. Participation in Conspiracy

GSK has also moved for summary judgment on the ground that it was not a co-conspirator to any allegedly anticompetitive arrangement.[51] GSK has put forward two arguments to support this contention: (1) it was not a co-conspirator because the "common scheme" to which it committed was not "designed to achieve an unlawful objective" as required by the Supreme Court's decision in Monsanto Co. v. Spray–Rite Service Corp., 465 U.S. 752, 104 S.Ct. 1464, 79 L.Ed.2d 775 (1984); and (2) there is no evidence that GSK's conduct was inconsistent with its independent interests and thus it cannot be liable under Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). The Court does not find either of these arguments persuasive.

To prove conspiracy under the antitrust laws, the plaintiffs must point to direct or circumstantial evidence in the summary judgement record that "reasonably tends to prove that [the parties] had a conscious commitment to a common scheme designed to achieve an unlawful objective." Monsanto, 465 U.S. at 768, 104 S.Ct. 1464; see also Edward J. Sweeney & Sons, Inc. v. Texaco, Inc., 637 F.2d 105, 111 (3d Cir.1980).

GSK's first argument—that it did not have an "unlawful objective" as required by Monsanto because (1) Judge Brody ordered that it participate in the settlement discussions; (2)

GSK requested that Judge Brody approve the settlement; and (3) GSK required that the Wellbutrin Settlement be subject to stronger FTC oversight—is not persuasive, because an intent to avoid liability does not protect conduct that has otherwise been found anticompetitive.

To withstand a summary judgment motion, the plaintiffs do not need to demonstrate that the defendants had the specific intent to restrain trade in reaching an agreement. See Times–Picayune Pub. Co. v. United States, 345 U.S. 594, 614–15, 73 S.Ct. 872, 97 L.Ed. 1277 (1953); see also National Collegiate Athletic Ass'n v. Board of Regents of Univ. of Oklahoma, 468 U.S. 85, 100–01 n. 23, 104 S.Ct. 2948, 82 L.Ed.2d 70 (1984)("it is...well settled that good motives will not validate an otherwise anticompetitive practice"); Geneva Pharma. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 507 (2d Cir.2004). The relevant intent is whether the defendants intended to enter the agreement itself, knowing of its unlawful objective. See Petruzzi's IGA Supermarkets, Inc. v. Darling–Delaware Co., Inc., 998 F.2d 1224, 1242–43 (3d Cir.1993)(evaluating a conspiracy based on alleged conscious parallelism).

The summary judgment record contains sufficient evidence for a reasonable jury to find that GSK intended to enter into the Wellbutrin Settlement, was in fact a party ***770** to the Wellbutrin Settlement, and understood its objective. GSK acknowledges that it (1) was involved in the settlement negotiations; (2) provided the Andrx sublicenses to Biovail; and (3) waived its rights to launch an authorized generic, an essential element of the Wellbutrin Settlement.[52] GSK was also a signatory to the Third Amendment to the Wellbutrin Settlement. The summary judgment record also shows that GSK understood the terms of the Wellbutrin Agreement.

GSK's argument that it participated in the Wellbutrin Settlement only to the extent that it was instructed to do so by Judge Brody appears to be a "reluctant conspirator" defense. Even reluctant participants, however, can be held liable for conspiracy. See Fineman v. Armstrong World Indus., Inc., 980 F.2d 171, 212 (3d Cir.1992); see also In re Processed Egg Prod. Antitrust Litig., 902 F.Supp.2d 704, 710 (E.D.Pa.2012). "Acquiescence to an illegal scheme is as much a violation of the Sherman Act as the creation and promotion of one." United States v. Paramount Pictures, 334 U.S. 131, 161, 68 S.Ct. 915, 92 L.Ed. 1260 (1948).

Second, GSK's argument regarding its independent motivation misconstrues the holdings of Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp. and its progeny. The Supreme Court's decision in Matsushita limits the range of permissible inferences from ambiguous indirect evidence of a conspiracy. 475 U.S. 574, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). In Matsushita, the Court found that to withstand summary judgment on an antitrust conspiracy claim, a plaintiff must present evidence that tends to exclude the possibility that an alleged conspirator acted independently. Id. at 588, 106 S.Ct. 1348. This requirement, however, applies only to claims supported by indirect evidence. In re Baby Food Antitrust Litig., 166 F.3d 112, 118 (3d Cir.1999); see also In re Flat Glass Antitrust Litig., 385 F.3d 350, 357 n. 7 (3d Cir.2004)("The strictures of Matsushita do not apply when a plaintiff provides direct evidence...").

Direct evidence of a conspiracy "obviates the need" for evidence that excludes the possibility of independent action. See In re Insurance Brokerage Antitrust Litig., 618 F.3d 300, 324 n. 23 (3d Cir.2010)("[D]irect evidence of a conspiracy, if credited, removes any ambiguities that might otherwise exist with respect to whether the parallel conduct in question is the result of independent or concerted action."). A signed agreement is direct evidence of a conspiracy. See Id. at 324.

GSK appears to be arguing that it was in its independent interest to join the agreement, not that it acted independent of any agreement. Because direct evidence of an agreement exists in the form of the Wellbutrin Settlement, however, an analysis under Matsushita is inappropriate. The existence of the Wellbutrin Settlement—an agreement—is sufficient evidence for a reasonable jury to find that GSK participated in the alleged conspiracy.

Although the summary judgment record does not contain evidence that GSK was a "calculating conspirator," and the Court recognizes that GSK went to great lengths to "safeguard against antitrust liability," given its desire to have Judge Brody approve the settlement and its insistence on enhanced FTC review, a reasonable jury could find that as a party to the agreement GSK was a co-conspirator and was not engaging in independent action. The Court, therefore, denies GSK's motion for ***771** summary judgement on the ground that it was not a co-conspirator.

An appropriate order shall issue.

All Citations

133 F.Supp.3d 734, 2016-1 Trade Cases P 79,535

Footnotes

1 The Supreme Court illustrated its understanding of reverse payment settlements as follows:

> Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement.

Actavis, 133 S.Ct. at 2227.

2 All facts herein are taken in the light most favorable to the plaintiffs. The plaintiffs, however, rely on a great deal of speculation in their recitation of the relevant facts; the Court will not consider the plaintiffs' speculation in deciding these motions. Summary judgment cannot be avoided by relying on speculation, and "inference based on speculation... does not create a material factual dispute." Robertson v. Allied Sig., Inc., 914 F.2d 360, 383 (3d Cir.1990).

3 The volume is officially known as the Approved Drug Products with Therapeutic Equivalents Evaluations.

4 On May 11, 2012, the Court found that the patent infringement actions brought by Biovail and GSK were not sham lawsuits and could not be the basis for antitrust liability. Wellbutrin XL, 2012 WL 1657734 at *17.

5 The Honorable James V. Selna presided over the Anchen litigation. GSK Stmt. ¶¶ 43, 44; Pls.' Stmt. Resp. ¶¶ 43, 44.

6 As the Court explained in detail in its decision granting summary judgment on the plaintiffs' sham litigation claims, FDA regulations require ANDA applicants to list all components used in the manufacture of the drug product, regardless of whether they appear in the drug product, as well as a statement of the composition of the drug product. 21 C.F.R. § 314.50. ANDA applicants must also "identify and characterize the inactive ingredients in the proposed drug product." Id. § 314.94(a)(9) (ii). In 2003, the FDA issued a "Guidance for Industry" that states:

> The function (i.e., role) of each component in the formulation should be stated. Components that are used in the manufacture of the drug product and do not appear in the finished drug product except at residual levels (e.g., some solvents) should be identified as processing agents.
>
> The target amount of each component by definite weight or other measure should be provided on a per unit basis.

2003 FDA Guidance at 8. Thus, in its pre-NDA submission to the FDA, the brand manufacturers of the original Wellbutrin IR had quantified a target amount per tablet of 0.5 mg of hydrochloric acid in the 50 mg formulation and 1.0 mg in the 100 mg formulation of Wellbutrin IR. Similarly, the NDA submitted for Wellbutrin SR indicated a target amount per tablet of 16.20 mg of cysteine hydrochloride, a different kind of acid stabilizer. The instruction to quantify the target amount of each component does not apply, however, to "processing agents." 2003 FDA Guidance 9. The FDA guidance does not clearly define "processing agent." See In re Wellbutrin XL Antitrust Litig., 2012 WL 1657734 at *9–11.

7 In November 2006, Andrx was acquired by Watson Pharmaceuticals; Watson had filed an ANDA to market generic 150mg Wellbutrin XL. Andrx was therefore not a "non-practicing" entity incapable of getting injunctive relief, as the plaintiffs have claimed. GSK Ex. 24.

8 The Court previously found that Biovail's citizen petition was not an independent basis for antitrust liability. In re Wellbutrin XL Antitrust Litig., 2012 WL 1657734 (E.D.Pa. May 11, 2012).

9 Anchen was a new company and, at the time it filed its ANDA for generic Wellbutrin XL, it had never launched or received FDA approval for a product. GSK Stmt. ¶ 21; Pls.' Stmt. Opp. ¶ 21.

10 In January 2006, Anchen had entered into an agreement with Teva and Impax whereby it allowed Teva to market any generic 300mg Wellbutrin XL made under Anchen's ANDA. If Anchen could not manufacture 300mg generic Wellbutrin XL, then Anchen would either relinquish its 180-day exclusivity or waive that exclusivity in favor of Impax. GSK Stmt. ¶ 23; Pls.' Stmt. Opp. ¶ 23.

Biovail had not filed an infringement action against Impax within the 45-day window provided by the Hatch-Waxman Act, so no 30-month stay of approval applied. Pls. Ex. 803; Pls. Stmt. Opp. ¶ 9, 23.

11 The plaintiffs' assertion that there was "no regulatory block to manufacturing and selling" Anchen's generic Wellbutrin XL is contradicted by the record. Pls. Opp'n at 11. Although the plaintiffs have argued that the Goodyear and Jeronimo facilities were the "same facility" for FDA inspection purposes, and that Anchen believed such a change only needed to be reported in Anchen's annual report to the FDA, both the FDA's and Anchen's conduct suggests otherwise. It is undisputed that upon learning of the manufacturing site change, the FDA in fact required Anchen to request, and Anchen did request, prior regulatory approval. GSK Ex. 72.

12 Biovail separately settled the Abrika litigation later. The Abrika settlement allowed for entry upon the expiration of Anchen's 180-day exclusivity period and there was no payment made in exchange for the agreement. Abrika received final FDA approval to market its 150mg version of generic Wellbutrin XL on August 15, 2008. GSK Stmt. ¶ 55; Pls.' Stmt. Opp. ¶ 55.

13 Prior to GSK's direct participation, GSK and Biovail had discussed the rights GSK may waive in a settlement and had shared draft settlement documents prior to GSK's actual involvement in settlement negotiations. For example, in early 2006 GSK informed Biovail that it was willing to "waive certain valuable rights to facilitate Biovail's desire to settle certain patent litigation," including its right to market an authorized generic. On December 16, 2006, counsel for GSK and Biovail discussed the settlement negotiations; on December 17, 2006, GSK received a draft of the settlement from Biovail for review. GSK Stmt. ¶ 56-57, 59; Pls.' Stmt. Opp. ¶ 56-57, 59.

14 The Wellbutrin Settlement also resolved the Watson litigation. The Watson settlement allowed for entry after Anchen's 180-day exclusivity period expired. Watson had received final FDA approval to market is 150mg version of generic Wellbutrin XL on January 31, 2007.

15 The plaintiffs argued in their opposition to GSK's motion for summary judgment that it was inappropriate for GSK not to notify the Federal Circuit that it had reached a settlement. It is unclear, however, how this is relevant to the antitrust question currently before the Court.

16 The Wellbutrin Settlement included seven total "triggers" for generic entry. See GSK Ex. 6 at 3.16.

17 The plaintiffs also rely on GSK and Biovail's 2007 SEC 20-F filings, which described the settlement as "allowing generic entry for the 150mg form in 2008." Pls. Exs. 698, 696. The filings, however, were made in February and March of 2008, respectively, so at that point it would have been impossible for the companies to report anything other than a 2008 generic launch.

18 Teva's antitrust counsel explained that it was Teva's "publicly stated" view at the time of the settlement that the Hatch-Waxman Act intended that "the first filing generic would be the only generic on the market." Holding Dep. Tr. 73:24-74:17.

19 The plaintiffs do not offer factual support for their allegation that "suddenly, and without explanation, the '708 patent license 'got put into' " the Wellbutrin Settlement. Rather, the generic manufacturers contemplated that the Wellbutrin Settlement would resolve the Andrx litigation. See Pls. Ex. 864; GSK Ex. 64.

Further, the plaintiffs make much of the fact that Andrx and Anchen may have possibly negotiated a settlement separate from the Wellbutrin Settlement. It is undisputed, however, that such a settlement was never memorialized or reached.

These points serve as examples of the speculation the Court cannot consider in deciding the motions for summary judgment.

20 Anchen told Andrx that it was planning a January 12, 2007 at risk launch of its 150mg product; Anchen said it was using its potential launch to facilitate settlement discussions with Andrx. GSK Stmt. ¶ 45; Pls.' Stmt. Opp. ¶ 45.

21 In an email from Teva's General Counsel to counsel for Biovail and GSK, Teva's counsel stated that "[t]he supply commitment can't be more watered down and useless—this wasn't the intent." Pls. Ex. 886.

22 The plaintiffs offer no factual support for their allegation that the parties to the Wellbutrin Settlement misled the FTC. It is undisputed that the FTC was provided with the entire Wellbutrin Settlement; the plaintiffs criticize the parties for failing to provide a "summary" of the agreements to the FTC, but it is unclear what benefit this would have had when the agency had access to the entire agreement. The parties to the settlement also met with both the head of and the deputy assistant director to the FTC's Health Care Division, which is specifically tasked with reviewing Hatch-Waxman patent settlement agreements. Holding Dep. Tr. 40:19-43:2.

23 The Court approved Biovail's settlement with the plaintiff classes on November 7, 2012, leaving GSK as the only defendant remaining in the case.

24 Under Federal Rule of Civil Procedure 56, a party moving for summary judgment must show that there is no genuine issue as to any material fact and that judgment is appropriate as a matter of law. Fed. R. Civ. P. 56(a). The moving party bears the initial burden of demonstrating the absence of any genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Once a properly supported motion for summary judgment is made, the burden shifts to the nonmoving party, who must set forth specific facts showing that there is a genuine issue for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. Id. at 247–48, 106 S.Ct. 2505.

The Court's analysis applies to both the plaintiffs' federal and state law claims except where otherwise noted.

25 In its motion for summary judgment, GSK also argued that Actavis does not apply to non-cash payments. This argument has been foreclosed by the Third Circuit's ruling in King Drug Co. of Florence, Inc. v. Smithkline Beecham, Corp., in which the court found that a no authorized generic agreement "falls under Actavis's rule because it may well represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition." 791 F.3d 388 at 393 (3d Cir.2015).

26 Because the Court has found that the Wellbutrin Settlement as a whole is not anticompetitive, it is not necessary to address whether these settlements—which were negotiated entry date only settlements in which no payment was made—are a basis for recovery.

27 In the event the Anchen litigation was not concluded before May 2008, or was concluded in favor of Biovail, a trigger date provided for the market entry of generic Wellbutrin XL.

28 In their briefs and at oral argument, the plaintiffs made much of the fact that the no authorized generic agreement may be valued at "$200 million." GSK has not moved for summary judgment on any grounds related to the value of the no authorized agreement, however, so the plaintiffs continued reliance on it is misplaced.

29 The plaintiffs offer no evidence to support their speculative claim that the "only reason" the Wellbutrin Settlement allowed the underlying patent litigation to continue was that it maintained Anchen's 180-day exclusivity period. The plaintiffs' expert Dr. Blume merely restates the Hatch-Waxman statutory scheme, which specifically allows a generic manufacturer to maintain its 180-day exclusivity period without launching so long as an appeal remains pending. See 21 U.S.C. § 355j(5)(D)(i)(I)(bb)(AA).

30 The Court is not aware of any other post-Actavis reverse payment patent settlement evaluated by courts that allowed the underlying patent litigation to continue, maintaining the risk of patent invalidity or a finding of non-infringement.

31 Although at oral argument the plaintiffs' counsel denied that he was advocating a presumption-based analysis, the plaintiffs' argument that they can demonstrate anticompetitive effects by showing a "large" payment and a delay appears to be such an analysis. See Oral Arg. Tr. at 58 ("A payment that the evidence shows is for delay that's large satisfies our first step.")

32 The plaintiffs have relied on King Drug of Florence, Inc. v. Cephalon, Inc. to support their argument that their required showing of anticompetitive effects is satisfied by showing a large payment. 88 F.Supp.3d 402, ——, 2015 WL 356913 at *10 (E.D.Pa. Jan. 28, 2015)("evidence of a large payment is required for a plaintiff to satisfy its initial burden of demonstrating anticompetitive effects under the Actavis rule of reason analysis."). The court in King Drug, however, was not faced with a settlement similar to the Wellbutrin Settlement. Rather, the court was evaluating a settlement that had ended the underlying patent litigation; the court, therefore, was faced the Wellbutrin Settlement allowed it to continue. As Actavis explained, the elimination of the risk of a patent litigation loss is the relevant harm in a rule of reason analysis.

33 The plaintiffs cite deposition testimony from three GSK witnesses: CEO Jean-Pierre Garnier, General Counsel Rupert Brondy, and Vice President Jack Davis. Davis testified that "there was a delay that [Teva] agreed to until, I believe, it was May 30th of 2008, or some earlier date, depending on some triggers which I don't know what those are." Davis Dep. Tr. 99:8-18. The plaintiffs failed to refer, however, to Davis's subsequent testimony that he could not testify to the specific relationship between the no authorized generic agreement and the negotiated trigger dates because he "wasn't involved in any of those conversations." Id. at 100:5-14. Similarly, Bondy testified that the fact that GSK would continue marketing 150mg Wellbutrin XL for a period of time without generic competition was a "significant term of the agreements." Bondy Dep. Tr. 110:15-19. Finally, Garnier testified that GSK "[sold] its exclusivity" back to Biovail to facilitate the settlement of the underlying patent litigation. Garnier 142:16-145:3.

34 The plaintiffs also cite a March 2007 internal GSK presentation that noted that as a result of the "deal" Teva would not market a generic Wellbutrin XL product until a "trigger date" and that GSK was barred from launching an authorized generic during the 180-day Hatch-Waxman exclusivity period. See Pls. Ex. 971. Although the document does address both elements of the deal, it does not present the "quid pro quo" that the plaintiffs suggest.

35 Such a showing may, however, satisfy the plaintiffs' prima facie burden under the Cartwright Act. In re Cipro Cases I & II, 61 Cal.4th 116, 187 Cal.Rptr.3d 632, 348 P.3d 845 (2015). As discussed below, however, the

Wellbutrin Settlement is not anticompetitive under the Court's full rule of reason analysis given the settlements procompetitive justifications.

36 GSK has filed a Daubert motion to exclude Dr. Leitzinger's testimony regarding a rule of reason analysis of the Wellbutrin Settlement on the grounds that Leitzinger has rested his analysis exclusively on counsel's instructions rather than an independent analysis of the summary judgment record.

The Court can decide GSK's motion for summary judgment, however, without deciding GSK's Daubert challenge of Dr. Leitzinger, because the Court relies on the undisputed facts in the summary judgment record. That said, Dr. Leitzinger's analysis of the Wellbutrin Settlement's effects are unreliable under Daubert and are excluded. Dr. Leitziner failed to analyze when and whether the generic manufacturers would have entered the market but for the Wellbutrin Settlement. Further, Dr. Leitzinger expressly failed to evaluate any procompetitive justifications of the Wellbutrin Settlement, making his already conclusory analysis fatally incomplete. Dr. Leitzinger's opinion is reciting only the plaintiffs' counsels' argument that the settlement is anticompetitive. His testimony regarding anticompetitive effects is unreliable.

37 Although the Lamictal court noted that it is not necessary at the motion to dismiss stage for the plaintiffs to present an alternate settlement scenario in order to establish anticompetitive effects, Lamictal, 791 F.3d at 410 (addressing the plaintiffs' burden at the motion to dismiss stage and finding that Actavis does not "require allegations that defendants could in fact have reached another, more competitive settlement."), it is one mechanism through which the plaintiffs may establish anticompetitive effects at the summary judgment stage.

38 GSK's contention that there is no evidence in the summary judgment record that it would have independently launched an authorized generic is not persuasive as to the lack of anticompetitive effects at the summary judgment stage. It was the promise of the no authorized generic, not only the failure of GSK to actually launch an authorized generic, that the plaintiffs claim caused the alleged anticompetitive effects in the form of delayed market entry for generic Wellbutrin XL. Even if the Court found that GSK had not planned to launch an authorized generic Wellbutrin XL product, there is no dispute that GSK made the promise that it would not do so.

39 There is no support in the summary judgment record for the plaintiffs' contention that the parties to the Wellbutrin Settlement concealed the nature of the settlement from the FTC. Rather, there is undisputed evidence in the summary judgment record that the parties to the settlement presented the entire settlement agreement to the FTC and met with the agency to explain the settlement.

40 Another reason why the Court has not considered the FTC's decisions to the Wellbutrin Settlement as evidence of either the lack of anticompetitive effects or the procompetitive nature of the settlement is that it is unlikely that the FTC's decision itself would be admissible on these topics. The circumstances surrounding the inclusion of the review provisions in the Wellbutrin Settlement and the submission of the settlement to the FTC, however, would be admissible at trial on a number of bases, including intent and the fact that enhanced FTC review had at least indirect procompetitive benefits.

41 Antitrust injury and causation are two essential elements of the doctrine of antitrust standing; the lack of antitrust standing prevents a plaintiff from recovering from the antitrust laws. Assoc. Gen. Contractors of Calif., Inc., v. California State Council of Carpenters, 459 U.S. 519, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983); Ethypharm S.A. France v. Abbott Labs., 707 F.3d 223, 232–33 (3d Cir.2013). If antitrust injury and causation are lacking, the Court does not need to address the remaining factors of antirust standing.

42 The Third Circuit in Lamictal did not address the issue of antitrust injury. Lamictal, 791 F.3d at 410 n. 35 ("we do not decide the question of antitrust injury in private actions such as this litigation...nor do we preclude the

parties from raising the issue on remand.")(citing Ian Simmons et al., Viewing Actavis Through The Lens of Clayton Act Section 4, Antitrust, Fall 2013, at 24). No other federal court of appeals has addressed the issue of antitrust injury in the context of reverse payment settlements.

43 The plaintiffs have mistakenly characterized GSK's argument that the patent cuts off the chain of causation as an "illegality defense" to antitrust claims. Courts have rejected such a defense. See Consolidated Exp., Inc. v. New York Shipping Ass'n, 602 F.2d 494, 525–26 (3d Cir.1979) (citing Perma Life Mufflers, Inc. v. Int'l Parts Corp., 392 U.S. 134, 88 S.Ct. 1981, 20 L.Ed.2d 982 (1968) (finding that the unclean hands defense was not applicable to antitrust violations)). GSK, however, is arguing that an independent regulation cut off the chain of causation that the plaintiffs are attempting to establish. The court in Consolidated Exp., Inc. did not address the issue of causation. It found only that the plaintiffs' violation of an unrelated law or regulation could not serve as a complete bar to antitrust liability. Notably, this case predates the Third Circuit's decision in City of Pittsburgh v. West Penn. Power.

44 Private plaintiffs cannot bring actions under the FTC Act.

45 The Court is not persuaded by the district court and California Supreme Court decisions that found that causation is satisfied by showing that the defendants' actions ended the patent litigation, making it unnecessary to consider the patent's validity. In re Cipro Cases I&II, 61 Cal.4th 116, 159, 187 Cal.Rptr.3d 632, 348 P.3d 845 (2015)("nothing in the United States Supreme Court's discussion of the legal rules at the boundary between antitrust and patent law hinged on the happenstance that the case under review involved a public prosecutor."); In re Aggrenox Antitrust Litig., No. 14–2516 2015 WL 4459607 at *9 (D.Conn. July 21, 2015). It appears to the Court that these decisions relax Section 4's causation requirement for the specific circumstance of challenges to reverse payment settlements. Additionally, even in Actavis, a case brought under the FTC Act, the Supreme Court said only that it is normally not necessary to litigate patent validity, not that such litigation would never be necessary.

The Court, however, is bound by the In re Cipro Cases decision in evaluating the indirect purchaser plaintiffs' claims under the California's Cartwright Act. Because the Court, however, has found that the Wellbutrin Settlement is not anticompetitive under the rule of reason, this does not alter the outcome of the summary judgment motion.

46 The plaintiffs have relied on Andrx Pharmaceuticals, Inc. v. Biovail Corp. Intl., 256 F.3d 799 (D.C.Cir.2001) and In re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir.2003), to support their argument that an at risk launch can support antitrust injury without evidence of success on the underlying patent claim. But neither case is persuasive in this context. Both cases were evaluating complaints at the motion to dismiss stage under a per se analysis. Both cases also predate—and are in conflict with—the Supreme Court's decision in Actavis (and the Third Circuit's decision in Lamictal) which control this decision.

47 The plaintiffs also challenge the reliability of Dr. Adelman's methodologies with respect to his opinions on the Biovail litigation. These challenges go to the weight of Dr. Adelman's testimony, not its admissibility. Because the Court finds in the plaintiffs' favor on the Biovail litigation, the plaintiffs' objections on this basis are moot.

48 Instead, they argue that Anchen/Teva would have reached a license agreement with Andrx. As discussed above, however, no license agreement exists between the parties and there is no evidence in the summary judgment record that an agreement would have been reached absent the Wellbutrin Settlement.

49 The plaintiffs' assertion that no law prohibited its production is counter to both FDA regulations and Anchen's conduct in response to FDA action.

50 Despite being given the opportunity, the plaintiffs declined to ask any witness from Anchen/Teva whether an at risk launch after June 2007 was planned. Instead, the plaintiffs chose to rely only on the documents that do not address the issue one way or another. See Oral Arg. Tr. at 68-69.

51 Because the Court will grant summary judgment on other grounds, there is no need for the Court also to decide this issue. But in an effort to be complete, the Court has considered all bases for summary judgment.

52 Although the defendants can argue—and have successfully argued—that the Wellbutrin Settlement is not anticompetitive, there is no question that GSK intended to participate in the settlement negotiations.

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119 S.Ct. 1604
Supreme Court of the United States

CALIFORNIA DENTAL ASSOCIATION, Petitioner,
v.
FEDERAL TRADE COMMISSION.

No. 97–1625
|
Argued Jan. 13, 1999.
|
Decided May 24, 1999.

Synopsis
Nonprofit state professional association of local dental societies petitioned for judicial review of order of Federal Trade Commission (FTC) requiring it to cease and desist from restricting certain types of advertising by member dentists. The United States Court of Appeals for the Ninth Circuit, 128 F.3d 720, affirmed FTC's order. After granting certiorari, the Supreme Court, Justice Souter, held that: (1) nonprofit professional association was subject to jurisdiction of FTC, and (2) abbreviated or "quick look" rule-of-reason analysis was not appropriate for association's advertising restrictions.

Vacated and remanded.

Justice Breyer filed opinion concurring in part and dissenting in part, in which Justices Stevens, Kennedy, and Ginsburg joined.

****1606** *Syllabus* [*]

Petitioner California Dental Association (CDA), a nonprofit association of local dental societies to which about three-quarters of the State's dentists belong, provides desirable insurance and preferential financing arrangements for its members, and engages in lobbying, litigation, marketing, and public relations for members' benefit. Members agree to abide by the CDA's Code of Ethics, which, *inter alia,* prohibits false or misleading advertising. The CDA has issued interpretive advisory opinions and guidelines relating to advertising. Respondent Federal Trade Commission brought a complaint, alleging that the CDA violated § 5 of the Federal Trade Commission Act (Act), 15 U.S.C. § 45, in applying its guidelines so as to restrict two types of truthful, nondeceptive advertising: price advertising, particularly discounted fees, and advertising relating to the quality of dental services. An Administrative Law Judge (ALJ) held the Commission to have jurisdiction over the CDA and found a § 5 violation. As relevant here, the Commission held that the advertising restrictions violated the Act under an abbreviated rule-of-reason analysis. In affirming, the Ninth Circuit sustained the Commission's jurisdiction and concluded that an abbreviated or "quick look" rule-of-reason analysis was proper in this case.

Held:

1. The Commission's jurisdiction extends to an association that, like the CDA, provides substantial economic benefit to its for-profit members. The Act gives the Commission authority over a "corporatio[n]," 15 U.S.C. § 45(a)(2), "organized to carry on business for its own profit or that of its members," § 44. The Commission's claim that the Act gives it jurisdiction over nonprofit associations whose activities provide substantial economic benefits to their for-profit members is clearly the better reading of the Act, which does not require that a supporting organization must devote itself entirely to its members' profits or say anything about how much of the entity's activities must go to raising the members' bottom lines. There is thus no apparent reason to let the Act's application turn on meeting some threshold percentage of activity for this purpose or even a softer formulation calling for a substantial part of the entity's total activities to be aimed at its members' pecuniary ***757** benefit. The Act does not cover all membership organizations of profit-making corporations without more. However, the economic benefits conferred upon CDA's profit-seeking professionals plainly fall within the object of enhancing its members' "profit," which is the Act's jurisdictional touchstone. The Act's logic and purpose comport with this result, and its legislative history is not inconsistent with this interpretation. Pp. 1610–1612.

2. Where any anticompetitive effects of given restraints are far from intuitively obvious, the rule of reason demands a more thorough enquiry into the consequences of those restraints than the abbreviated analysis the Ninth Circuit performed in this case. Pp. 1612–1618.

(a) An abbreviated or "quick-look" analysis is appropriate when an observer with even a rudimentary understanding of economics could conclude that the arrangements in question have an anticompetitive effect on customers and markets. See, *e.g., National Collegiate Athletic Assn. v. Board of Regents of*

Univ. of Okla., 468 U.S. 85, 104 S.Ct. 2948, 82 L.Ed.2d 70. This case fails to present a situation in which the likelihood of anticompetitive effects is comparably obvious, for the CDA's advertising restrictions might plausibly be thought to have a net procompetitive effect or possibly no effect at all on competition. Pp. 1612–1613.

(b) The discount and nondiscount advertising restrictions are, on their face, designed ****1607** to avoid false or deceptive advertising in a market characterized by striking disparities between the information available to the professional and the patient. The existence of significant challenges to informed decisionmaking by the customer for professional services suggests that advertising restrictions arguably protecting patients from misleading or irrelevant advertising call for more than cursory treatment. In applying cursory review, the Ninth Circuit brushed over the professional context and described no anticompetitive effects from the discount advertising bar. The CDA's price advertising rule appears to reflect the prediction that any costs to competition associated with eliminating across-the-board advertising will be outweighed by gains to consumer information created by discount advertising that is exact, accurate, and more easily verifiable. This view may or may not be correct, but it is not implausible; and neither a court nor the Commission may initially dismiss it as presumptively wrong. The CDA's plausible explanation for its nonprice advertising restrictions, namely that restricting unverifiable quality claims would have a procompetitive effect by preventing misleading or false claims that distort the market, likewise rules out the Ninth Circuit's use of abbreviated rule-of-reason analysis for those restrictions. The obvious anticompetitive effect that triggers such analysis has not been shown. Pp. 1613–1616.

***758** (c) Saying that the Ninth Circuit's conclusion required a more extended examination of the possible factual underpinnings than it received is not necessarily to call for the fullest market analysis. Not every case attacking a restraint not obviously anticompetitive is a candidate for plenary market examination. There is generally no categorical line between restraints giving rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment. What is required is an enquiry meet for the case, looking to a restraint's circumstances, details, and logic. Here, a less quick look was required for the initial assessment of the CDA's advertising restrictions. Pp. 1617–1618.

128 F.3d 720, vacated and remanded.

SOUTER, J., delivered the opinion for a unanimous Court with respect to Parts I and II, and the opinion of the Court with respect to Part III, in which REHNQUIST, C. J., and O'CONNOR, SCALIA, and THOMAS, JJ., joined. BREYER, J., filed an opinion concurring in part and dissenting in part, in which STEVENS, KENNEDY, and GINSBURG, JJ., joined, *post,* p. 1618.

Attorneys and Law Firms

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Lawrence G. Wallace, Washington, D.C., for respondent.

Opinion

***759** Justice SOUTER delivered the opinion of the Court.

There are two issues in this case: whether the jurisdiction of the Federal Trade Commission extends to the California Dental Association (CDA), a nonprofit professional association, and whether a "quick look" sufficed to justify finding that certain advertising restrictions adopted by the CDA violated the antitrust laws. We hold that the Commission's jurisdiction under the Federal Trade Commission Act (FTC Act) extends to an association that, like the CDA, provides substantial economic benefit to its for-profit members, but that where, as here, any anticompetitive effects of given restraints are far from intuitively obvious, the rule of reason demands a more thorough enquiry into the consequences of those restraints than the Court of Appeals performed.

I

The CDA is a voluntary nonprofit association of local dental societies to which some 19,000 dentists belong, including about three-quarters of those practicing in the State. *In re California Dental Assn.,* 121 F.T.C. 190, 196–197 (1996). The CDA is exempt from federal income tax under ****1608** 26 U.S.C. § 501(c)(6), covering "[b]usiness leagues, chambers ***760** of commerce, real-estate boards, [and] boards of trade," although it has for-profit subsidiaries that give its members advantageous access to various sorts of insurance, including liability coverage, and to financing for their real estate, equipment, cars, and patients' bills. The CDA lobbies and litigates in its members' interests, and conducts marketing and public relations campaigns for their benefit. 128 F.3d 720, 723 (C.A.9 1997).

The dentists who belong to the CDA through these associations agree to abide by a Code of Ethics (Code) including the following § 10:

> "Although any dentist may advertise, no dentist shall advertise or solicit patients in any form of communication in a manner that is false or misleading in any material respect. In order to properly serve the public, dentists should represent themselves in a manner that contributes to the esteem of the public. Dentists should not misrepresent their training and competence in any way that would be false or misleading in any material respect." App. 33.

The CDA has issued a number of advisory opinions interpreting this section, [1] and through separate advertising ***761** guidelines intended to help members comply with the Code and with state law the CDA has advised its dentists of disclosures they must make under state law when engaging in discount advertising. [2]

Responsibility for enforcing the Code rests in the first instance with the local dental societies, to which applicants for CDA membership must submit copies of their own advertisements and those of their employers or referral services to assure compliance with the Code. The local societies also actively seek information about potential Code violations by applicants or CDA members. Applicants who refuse to withdraw or revise objectionable advertisements may be denied membership; and members who, after a hearing, remain ***762** similarly recalcitrant are subject to censure, suspension, or expulsion from the CDA. 128 F.3d, at 724.

The Commission brought a complaint against the CDA, alleging that it applied its guidelines so as to restrict truthful, nondeceptive advertising, and so violated § 5 of the FTC Act, 38 Stat. 717, 15 U.S.C. § 45. [3] The ****1609** complaint alleged that the CDA had unreasonably restricted two types of advertising: price advertising, particularly discounted fees, and advertising relating to the quality of dental services. Complaint ¶ 7. An Administrative Law Judge (ALJ) held the Commission to have jurisdiction over the CDA, which, the ALJ noted, had itself "stated that a selection of its programs and services has a potential value to members of between $22,739 and $65,127," 121 F.T.C., at 207. He found that, although there had been no proof that the CDA exerted market power, no such proof was required to establish an antitrust violation under *In re Mass. Bd. of Registration in Optometry,* 110 F.T.C. 549 (1988), since the CDA had unreasonably prevented members and potential members from using truthful, nondeceptive advertising, all to the detriment of both dentists and consumers of dental services. He accordingly found a violation of § 5 of the FTC Act. 121 F.T.C., at 272–273.

The Commission adopted the factual findings of the ALJ except for his conclusion that the CDA lacked market power, with which the Commission disagreed. The Commission treated the CDA's restrictions on discount advertising as illegal *per se.* 128 F.3d, at 725. In the alternative, the Commission held the price advertising (as well as the nonprice) restrictions to be violations of the Sherman and FTC Acts ***763** under an abbreviated rule-of-reason analysis. One Commissioner concurred separately, arguing that the Commission should have applied the *Mass. Bd.* standard, not the *per se* analysis, to the limitations on price advertising. Another Commissioner dissented, finding the evidence insufficient to show either that the restrictions had an anticompetitive effect under the rule of reason, or that the CDA had market power. 128 F.3d, at 725.

The Court of Appeals for the Ninth Circuit affirmed, sustaining the Commission's assertion of jurisdiction over the CDA and its ultimate conclusion on the merits. *Id.,* at 730. The court thought it error for the Commission to have applied *per se* analysis to the price advertising restrictions, finding analysis under the rule of reason required for all the restrictions. But the Court of Appeals went on to explain that the Commission had properly

> "applied an abbreviated, or 'quick look,' rule of reason analysis designed for restraints that are not per se unlawful but are sufficiently anticompetitive on their face that they do not require a full-blown rule of reason inquiry. *See* [*National Collegiate Athletic Assn. v. Board of Regents of Univ. of Okla.,* 468 U.S. 85, 109–110, and n. 39, 104 S.Ct. 2948, 82 L.Ed.2d 70 (1984)] ('The essential point is that the rule of reason can sometimes be applied in the twinkling of an eye.') [*Ibid.* (citing P. Areeda, The "Rule of Reason" in Antitrust Analysis: General Issues 37–38 (Federal Judicial Center, June 1981) (parenthetical omitted)).] It allows the condemnation of a 'naked restraint' on price or output without an 'elaborate industry analysis.' *Id.* at 109, 104 S.Ct. 2948." *Id.,* at 727, 104 S.Ct. 2948.

The Court of Appeals thought truncated rule-of-reason analysis to be in order for several reasons. As for the restrictions on discount advertising, they "amounted in

practice to a fairly 'naked' restraint on price competition itself," *ibid.* The CDA's procompetitive justification, that the restrictions ***764** encouraged disclosure and prevented false and misleading advertising, carried little weight because "it is simply infeasible to disclose all of the information that is required," *id.,* at 728, and "the record provides no evidence that the rule has in fact led to increased disclosure and transparency of dental pricing," *ibid.* As to nonprice advertising restrictions, the court said that

> "[t]hese restrictions are in effect a form of output limitation, as they restrict the supply of information about individual dentists' services. *See* Areeda & Hovenkamp, *Antitrust Law* ¶ 1505 at 693–94 (Supp.1997).... The restrictions may also affect ****1610** output more directly, as quality and comfort advertising may induce some customers to obtain nonemergency care when they might not otherwise do so.... Under these circumstances, we think that the restriction is a sufficiently naked restraint on output to justify quick look analysis." *Ibid.*

The Court of Appeals went on to hold that the Commission's findings with respect to the CDA's agreement and intent to restrain trade, as well as on the effect of the restrictions and the existence of market power, were all supported by substantial evidence. *Id.,* at 728–730. In dissent, Judge Real took the position that the Commission's jurisdiction did not cover the CDA as a nonprofit professional association engaging in no commercial operations. *Id.,* at 730. But even assuming jurisdiction, he argued, full-bore rule-of-reason analysis was called for, since the disclosure requirements were not naked restraints and neither fixed prices nor banned nondeceptive advertising. *Id.,* at 730–731.

We granted certiorari to resolve conflicts among the Circuits on the Commission's jurisdiction over a nonprofit professional association [4] and the occasions for abbreviated ***765** rule-of-reason analysis. [5] 524 U.S. 980, 119 S.Ct. 29, 141 L.Ed.2d 789 (1998). We now vacate the judgment of the Court of Appeals and remand.

II

The FTC Act gives the Commission authority over "persons, partnerships, or corporations," 15 U.S.C. § 45(a)(2), and defines "corporation" to include "any company ... or association, incorporated or unincorporated, without shares of capital or capital stock or certificates of interest, except partnerships, which is organized to carry on business for its own profit or that of its members," § 44. Although the Circuits have not agreed on the precise extent of this definition, see n. 4, *supra,* the Commission has long held that some circumstances give it jurisdiction over an entity that seeks no profit for itself. While the Commission has claimed to have jurisdiction over a nonprofit entity if a substantial part of its total activities provides pecuniary benefits to its members, see *In re American Medical Assn.,* 94 F.T.C. 701, 983–984 (1979), respondent now advances the slightly different formulation that the Commission has jurisdiction "over anticompetitive practices by nonprofit associations whose activities provid[e] substantial economic benefits to their for-profit members' businesses." Brief for Respondent 20.

Respondent urges deference to this interpretation of the Commission's jurisdiction as reasonable. *Id.,* at 25–26 (citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984), ***766** *Mississippi Power & Light Co. v. Mississippi ex rel. Moore,* 487 U.S. 354, 380–382, 108 S.Ct. 2428, 101 L.Ed.2d 322 1988) (SCALIA, J., concurring) (*Chevron* deference applies to agency's interpretation of its own statutory jurisdiction)). But we have no occasion to review the call for deference here, the interpretation urged in respondent's brief being clearly the better reading of the statute under ordinary principles of construction.

The FTC Act is at pains to include not only an entity "organized to carry on business for its own profit," 15 U.S.C. § 44, but also one that carries on business for the profit "of its members," *ibid.* While such a supportive organization may be devoted to helping its members in ways beyond immediate enhancement of profit, no one here has claimed that such an entity must devote itself single-mindedly to the profit of others. It ****1611** could, indeed, hardly be supposed that Congress intended such a restricted notion of covered supporting organizations, with the opportunity this would bring with it for avoiding jurisdiction where the purposes of the FTC Act would obviously call for asserting it.

Just as the FTC Act does not require that a supporting organization must devote itself entirely to its members' profits, neither does the Act say anything about how much of the entity's activities must go to raising the members' bottom lines. There is accordingly no apparent reason to let the statute's application turn on meeting some threshold percentage of activity for this purpose, or even satisfying a softer formulation calling for a substantial part of the

nonprofit entity's total activities to be aimed at its members' pecuniary benefit. To be sure, proximate relation to lucre must appear; the FTC Act does not cover all membership organizations of profit-making corporations without more, and an organization devoted solely to professional education may lie outside the FTC Act's jurisdictional reach, even though the quality of professional services ultimately affects the profits of those who deliver them.

There is no line drawing exercise in this case, however, where the CDA's contributions to the profits of its individual ***767** members are proximate and apparent. Through for-profit subsidiaries, the CDA provides advantageous insurance and preferential financing arrangements for its members, and it engages in lobbying, litigation, marketing, and public relations for the benefit of its members' interests. This congeries of activities confers far more than *de minimis* or merely presumed economic benefits on CDA members; the economic benefits conferred upon the CDA's profit-seeking professionals plainly fall within the object of enhancing its members' "profit,"[6] which the FTC Act makes the jurisdictional touchstone. ***768** There is no difficulty in concluding that the Commission has jurisdiction over the CDA.

The logic and purpose of the FTC Act comport with this result. The FTC Act directs the Commission to "prevent" the broad set of entities under its jurisdiction "from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(2). Nonprofit entities organized on behalf of for-profit members have the same capacity and derivatively, at least, ****1612** the same incentives as for-profit organizations to engage in unfair methods of competition or unfair and deceptive acts. It may even be possible that a nonprofit entity up to no good would have certain advantages, not only over a for-profit member but over a for-profit membership organization as well; it would enjoy the screen of superficial disinterest while devoting itself to serving the interests of its members without concern for doing more than breaking even.

Nor, contrary to petitioner's argument, is the legislative history inconsistent with this interpretation of the Commission's jurisdiction. Although the versions of the FTC Act first passed by the House and the Senate defined "corporation" to refer only to incorporated, joint stock, and share-capital companies organized to carry on business for profit, see H.R. Conf. Rep. No. 1142, 63d Cong., 2d Sess., 11, 14 (1914), the Conference Committee subsequently revised the definition to its present form, an alteration that indicates an ***769** intention to include nonprofit entities.[7] And the legislative history, like the text of the FTC Act, is devoid of any hint at an exemption for professional associations as such.

We therefore conclude that the Commission had jurisdiction to pursue the claim here, and turn to the question whether the Court of Appeals devoted sufficient analysis to sustain the claim that the advertising restrictions promulgated by the CDA violated the FTC Act.

III

The Court of Appeals treated as distinct questions the sufficiency of the analysis of anticompetitive effects and the substantiality of the evidence supporting the Commission's conclusions. Because we decide that the Court of Appeals erred when it held as a matter of law that quick-look analysis was appropriate (with the consequence that the Commission's abbreviated analysis and conclusion were sustainable), we do not reach the question of the substantiality of the evidence supporting the Commission's conclusion.[8]

In *National Collegiate Athletic Assn. v. Board of Regents of Univ. of Okla.,* 468 U.S. 85, 104 S.Ct. 2948, 82 L.Ed.2d 70 (1984), we held that a "naked restraint on price and output requires some competitive justification ***770** even in the absence of a detailed market analysis." *Id.,* at 110, 104 S.Ct. 2948. Elsewhere, we held that "no elaborate industry analysis is required to demonstrate the anticompetitive character of " horizontal agreements among competitors to refuse to discuss prices, *National Soc. of Professional Engineers v. United States,* 435 U.S. 679, 692, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978), or to withhold a particular desired service, *FTC v. Indiana Federation of Dentists,* 476 U.S. 447, 459, 106 S.Ct. 2009, 90 L.Ed.2d 445 (1986) (quoting *National Soc. of Professional Engineers, supra,* at 692, 98 S.Ct. 1355). In each of these cases, which have formed the basis for what has come to be called abbreviated or "quick-look" analysis under the rule of reason, an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets. In *National Collegiate Athletic Assn.,* the league's television plan expressly limited output (the number of games that could be televised) and fixed a minimum price. 468 U.S., at 99–100, 104 S.Ct. 2948. In ****1613** *National Soc. of Professional Engineers,*

the restraint was "an absolute ban on competitive bidding." 435 U.S., at 692, 98 S.Ct. 1355. In *Indiana Federation of Dentists,* the restraint was "a horizontal agreement among the participating dentists to withhold from their customers a particular service that they desire." 476 U.S., at 459, 106 S.Ct. 2009. As in such cases, quick-look analysis carries the day when the great likelihood of anticompetitive effects can easily be ascertained. See *Law v. National Collegiate Athletic Assn.,* 134 F.3d 1010, 1020 (C.A.10 1998) (explaining that quick-look analysis applies "where a practice has obvious anticompetitive effects"); *Chicago Professional Sports Limited Partnership v. National Basketball Assn.,* 961 F.2d 667, 674–676 (C.A.7 1992) (finding quick-look analysis adequate after assessing and rejecting logic of proffered procompetitive justifications); cf. *United States v. Brown University,* 5 F.3d 658, 677–678 (C.A.3 1993) (finding full rule-of-reason analysis required where universities sought to provide financial aid to needy students and noting by way of contrast that the agreements ***771** in *National Soc. of Professional Engineers* and *Indiana Federation of Dentists* "embodied a strong economic self-interest of the parties to them").

The case before us, however, fails to present a situation in which the likelihood of anticompetitive effects is comparably obvious. Even on Justice BREYER's view that bars on truthful and verifiable price and quality advertising are *prima facie* anticompetitive, see *post,* at 1619–1620 (opinion concurring in part and dissenting in part), and place the burden of procompetitive justification on those who agree to adopt them, the very issue at the threshold of this case is whether professional price and quality advertising is sufficiently verifiable in theory and in fact to fall within such a general rule. Ultimately our disagreement with Justice BREYER turns on our different responses to this issue. Whereas he accepts, as the Ninth Circuit seems to have done, that the restrictions here were like restrictions on advertisement of price and quality generally, see, *e.g., post,* at 1620, 1621, 1622, it seems to us that the CDA's advertising restrictions might plausibly be thought to have a net procompetitive effect, or possibly no effect at all on competition. The restrictions on both discount and nondiscount advertising are, at least on their face, designed to avoid false or deceptive advertising[9] in a market characterized by striking disparities between the information available to the professional and the patient.[10] Cf. ***772** Carr & Mathewson, The Economics of Law Firms: A Study in the Legal Organization of the Firm, 33 J. Law & Econ. 307, 309 (1990) (explaining that in a market for complex professional services, "inherent asymmetry of knowledge about the product" arises because "professionals supplying the good are knowledgeable [whereas] consumers demanding the good are uninformed"); Akerlof, The Market for "Lemons": Quality Uncertainty and the Market Mechanism, 84 Q.J. Econ. 488 (1970) (pointing out quality problems in market characterized by asymmetrical information). In a market for professional services, in which advertising is relatively rare and the comparability of service packages not easily established, the difficulty for customers or potential competitors to get and verify information about the price and availability of services magnifies the dangers to competition associated with misleading advertising. What is more, the quality of professional services tends to resist either calibration or monitoring by individual patients or clients, partly because of the specialized knowledge required ****1614** to evaluate the services, and partly because of the difficulty in determining whether, and the degree to which, an outcome is attributable to the quality of services (like a poor job of tooth filling) or to something else (like a very tough walnut). See Leland, Quacks, Lemons, and Licensing: A Theory of Minimum Quality Standards, 87 J. Pol. Econ. 1328, 1330 (1979); 1 B. Furrow, T. Greaney, S. Johnson, T. Jost, & R. Schwartz, Health Law § 3–1, p. 86 (1995) (describing the common view that "the lay public is incapable of adequately evaluating the quality of medical services"). Patients' attachments to particular professionals, the rationality of which is difficult to assess, complicate the picture even further. Cf. Evans, Professionals and the Production Function: Can Competition Policy Improve Efficiency in the Licensed Professions?, in Occupational Licensure and Regulation 235–236 (S. Rottenberg ***773** ed.1980) (describing long-term relationship between professional and client not as "a series of spot contracts" but rather as "a long-term agreement, often implicit, to deal with each other in a set of future unspecified or incompletely specified circumstances according to certain rules," and adding that "[i]t is not clear how or if these [implicit contracts] can be reconciled with the promotion of effective price competition in individual spot markets for particular services"). The existence of such significant challenges to informed decisionmaking by the customer for professional services immediately suggests that advertising restrictions arguably protecting patients from misleading or irrelevant advertising call for more than cursory treatment as obviously comparable to classic horizontal agreements to limit output or price competition.

The explanation proffered by the Court of Appeals for the likely anticompetitive effect of the CDA's restrictions

on discount advertising began with the unexceptionable statements that "price advertising is fundamental to price competition," 128 F.3d, at 727, and that "[r]estrictions on the ability to advertise prices normally make it more difficult for consumers to find a lower price and for dentists to compete on the basis of price," *ibid.* (citing *Bates v. State Bar of Ariz.,* 433 U.S. 350, 364, 97 S.Ct. 2691, 53 L.Ed.2d 810 (1977); *Morales v. Trans World Airlines, Inc.,* 504 U.S. 374, 388, 112 S.Ct. 2031, 119 L.Ed.2d 157 (1992)). The court then acknowledged that, according to the CDA, the restrictions nonetheless furthered the "legitimate, indeed procompetitive, goal of preventing false and misleading price advertising." 128 F.3d, at 728. The Court of Appeals might, at this juncture, have recognized that the restrictions at issue here are very far from a total ban on price or discount advertising, and might have considered the possibility that the particular restrictions on professional advertising could have different effects from those "normally" found in the commercial world, even to the point of promoting competition by reducing the occurrence of unverifiable and misleading across-the-board ***774** discount advertising. [11] Instead, the Court of Appeals confined itself to the brief assertion that the "CDA's disclosure requirements appear to prohibit across-the-board discounts because it is simply infeasible to disclose all of the information that is required," *ibid.,* followed by the observation that "the record provides no evidence that the rule has in fact led to increased disclosure and transparency of dental pricing," *ibid.*

But these observations brush over the professional context and describe no anticompetitive effects. Assuming that the record in fact supports the conclusion that the CDA disclosure rules essentially bar advertisement of across-the-board discounts, it does not obviously follow that such a ban would have a net anticompetitive effect here. Whether advertisements that announced discounts for, say, first-time customers, would be less effective at conveying information relevant to competition if they listed the original ****1615** and discounted prices for checkups, X-rays, and fillings, than they would be if they simply specified a percentage discount across the board, seems to us a question susceptible to empirical but not *a priori* analysis. In a suspicious world, the discipline of specific example may well be a necessary condition of plausibility for professional claims that for all practical purposes defy comparison shopping. It is also possible in principle that, even if across-the-board discount advertisements were more effective in drawing customers in the short run, the recurrence of some measure of intentional or accidental misstatement due to the breadth of their claims might ***775** leak out over time to make potential patients skeptical of any such across-the-board advertising, so undercutting the method's effectiveness. Cf. Akerlof, 84 Q.J. Econ., at 495 (explaining that "dishonest dealings tend to drive honest dealings out of the market"). It might be, too, that across-the-board discount advertisements would continue to attract business indefinitely, but might work precisely because they were misleading customers, and thus just because their effect would be anticompetitive, not procompetitive. Put another way, the CDA's rule appears to reflect the prediction that any costs to competition associated with the elimination of across-the-board advertising will be outweighed by gains to consumer information (and hence competition) created by discount advertising that is exact, accurate, and more easily verifiable (at least by regulators). As a matter of economics this view may or may not be correct, but it is not implausible, and neither a court nor the Commission may initially dismiss it as presumptively wrong. [12]

In theory, it is true, the Court of Appeals neither ruled out the plausibility of some procompetitive support for the CDA's requirements nor foreclosed the utility of an evidentiary discussion on the point. The court indirectly acknowledged the plausibility of procompetitive justifications for the ***776** CDA's position when it stated that "the record provides no evidence that the rule has in fact led to increased disclosure and transparency of dental pricing," 128 F.3d, at 728. But because petitioner alone would have had the incentive to introduce such evidence, the statement sounds as though the Court of Appeals may have thought it was justified without further analysis to shift a burden to the CDA to adduce hard evidence of the procompetitive nature of its policy; the court's adversion to empirical evidence at the moment of this implicit burden shifting underscores the leniency of its enquiry into evidence of the restrictions' anticompetitive effects.

The Court of Appeals was comparably tolerant in accepting the sufficiency of abbreviated rule-of-reason analysis as to the nonprice advertising restrictions. The court began with the argument that "[t]hese restrictions are in effect a form of output limitation, as they restrict the supply of information about individual dentists' services." *Ibid.* (citing P. Areeda & H. Hovenkamp, Antitrust Law ¶ 1505, pp. 693–694 (1997 Supp.)). Although this sentence does indeed appear as cited, it is puzzling, given that the relevant output for antitrust purposes here is presumably not information or advertising, but dental services themselves. The question is not whether the universe of possible advertisements has been limited (as assuredly it has), but whether the limitation on advertisements obviously tends to limit the total delivery

of dental services. The court came closest to addressing this latter question **1616 when it went on to assert that limiting advertisements regarding quality and safety "prevents dentists from fully describing the package of services they offer," 128 F.3d, at 728, adding that "[t]he restrictions may also affect output more directly, as quality and comfort advertising may induce some customers to obtain nonemergency care when they might not otherwise do so," *ibid.* This suggestion about output is also puzzling. If quality advertising actually induces some patients to obtain more care *777 than they would in its absence, then restricting such advertising would reduce the demand for dental services, not the supply; and it is of course the producers' supply of a good in relation to demand that is normally relevant in determining whether a producer-imposed output limitation has the anticompetitive effect of artificially raising prices, [13] see *General Leaseways, Inc. v. National Truck Leasing Assn.,* 744 F.2d 588, 594–595 (C.A.7 1984) ("An agreement on output also equates to a price-fixing agreement. If firms raise price, the market's demand for their product will fall, so the amount supplied will fall too—in other words, output will be restricted. If instead the firms restrict output directly, price will as mentioned rise in order to limit demand to the reduced supply. Thus, with exceptions not relevant here, raising price, reducing output, and dividing markets have the same anticompetitive effects").

Although the Court of Appeals acknowledged the CDA's view that "claims about quality are inherently unverifiable and therefore misleading," 128 F.3d, at 728, it responded that this concern "does not justify banning all quality claims without regard to whether they are, in fact, false or misleading," *ibid.* As a result, the court said, "the restriction is a sufficiently naked restraint on output to justify quick look analysis." *Ibid.* The court assumed, in these words, that some dental quality claims may escape justifiable censure, because they are both verifiable and true. But its implicit *778 assumption fails to explain why it gave no weight to the countervailing, and at least equally plausible, suggestion that restricting difficult-to-verify claims about quality or patient comfort would have a procompetitive effect by preventing misleading or false claims that distort the market. It is, indeed, entirely possible to understand the CDA's restrictions on unverifiable quality and comfort advertising as nothing more than a procompetitive ban on puffery, cf. *Bates,* 433 U.S., at 366, 97 S.Ct. 2691 (claims relating to the quality of legal services "probably are not susceptible of precise measurement or verification and, under some circumstances, might well be deceptive or misleading to the public, or even false"); *id.,* at 383–384, 97 S.Ct. 2691 ("[A]dvertising claims as to the quality of services ... are not susceptible of measurement or verification; accordingly, such claims may be so likely to be misleading as to warrant restriction"), notwithstanding Justice BREYER's citation (to a Commission discussion that never faces the issue of the unverifiability of professional quality claims, raised in *Bates*), *post,* at 1620. [14]

The point is not that the CDA's restrictions necessarily have the procompetitive effect claimed by the CDA; it is possible that banning quality claims might have no effect at all on competitiveness if, for example, many dentists made very much the same sort of claims. And it is also of course possible that the restrictions might in the final analysis be anticompetitive. The point, rather, is that the plausibility of competing claims **1617 about the effects of the professional advertising restrictions rules out the indulgently abbreviated review to which the Commission's order was treated. The obvious anticompetitive effect that triggers abbreviated analysis has not been shown.

*779 In light of our focus on the adequacy of the Court of Appeals's analysis, Justice BREYER's thorough-going, *de novo* antitrust analysis contains much to impress on its own merits but little to demonstrate the sufficiency of the Court of Appeals's review. The obligation to give a more deliberate look than a quick one does not arise at the door of this Court and should not be satisfied here in the first instance. Had the Court of Appeals engaged in a painstaking discussion in a league with Justice BREYER's (compare his 14 pages with the Ninth Circuit's 8), and had it confronted the comparability of these restrictions to bars on clearly verifiable advertising, its reasoning might have sufficed to justify its conclusion. Certainly Justice BREYER's treatment of the antitrust issues here is no "quick look." Lingering is more like it, and indeed Justice BREYER, not surprisingly, stops short of endorsing the Court of Appeals's discussion as adequate to the task at hand.

Saying here that the Court of Appeals's conclusion at least required a more extended examination of the possible factual underpinnings than it received is not, of course, necessarily to call for the fullest market analysis. Although we have said that a challenge to a "naked restraint on price and output" need not be supported by "a detailed market analysis" in order to "requir[e] some competitive justification," *National Collegiate Athletic Assn.,* 468 U.S., at 110, 104 S.Ct. 2948, it does not follow that every case attacking a less obviously anticompetitive restraint (like this one) is a candidate for

plenary market examination. The truth is that our categories of analysis of anticompetitive effect are less fixed than terms like "*per se,*" "quick look," and "rule of reason" tend to make them appear. We have recognized, for example, that "there is often no bright line separating *per se* from Rule of Reason analysis," since "considerable inquiry into market conditions" may be required before the application of any so-called "*per se* " condemnation is justified. *Id.,* at 104, n. 26, 104 S.Ct. 2948. "[W]hether the ultimate finding is the product of a presumption or actual ***780** market analysis, the essential inquiry remains the same—whether or not the challenged restraint enhances competition." *Id.,* at 104, 104 S.Ct. 2948. Indeed, the scholar who enriched antitrust law with the metaphor of "the twinkling of an eye" for the most condensed rule-of-reason analysis himself cautioned against the risk of misleading even in speaking of a "spectrum" of adequate reasonableness analysis for passing upon antitrust claims: "There is always something of a sliding scale in appraising reasonableness, but the sliding scale formula deceptively suggests greater precision than we can hope for.... Nevertheless, the quality of proof required should vary with the circumstances." P. Areeda, Antitrust Law ¶ 1507, p. 402 (1986). [15] At the same time, Professor Areeda also emphasized the necessity, particularly great in the quasi-common-law realm of antitrust, that courts explain the logic of their conclusions. "By exposing their reasoning, judges ... are subjected to others' critical analyses, which in turn can lead to better understanding for the future." *Id.,* ¶ 1500, at 364. As ****1618** the circumstances here demonstrate, there is generally no categorical line to be drawn between ***781** restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment. What is required, rather, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint. The object is to see whether the experience of the market has been so clear, or necessarily will be, that a confident conclusion about the principal tendency of a restriction will follow from a quick (or at least quicker) look, in place of a more sedulous one. And of course what we see may vary over time, if rule-of-reason analyses in case after case reach identical conclusions. For now, at least, a less quick look was required for the initial assessment of the tendency of these professional advertising restrictions. Because the Court of Appeals did not scrutinize the assumption of relative anticompetitive tendencies, we vacate the judgment and remand the case for a fuller consideration of the issue.

It is so ordered.

Justice BREYER, with whom Justice STEVENS, Justice KENNEDY, and Justice GINSBURG join, concurring in part and dissenting in part.

I agree with the Court that the Federal Trade Commission (FTC or Commission) has jurisdiction over petitioner, and I join Parts I and II of its opinion. I also agree that in a "rule of reason" antitrust case "the quality of proof required should vary with the circumstances," that "[w]hat is required ... is an enquiry meet for the case," and that the object is a "confident conclusion about the principal tendency of a restriction." *Ante,* at 1617–1618 (internal quotation marks omitted). But I do not agree that the Court has properly applied those unobjectionable principles here. In my view, a traditional application of the rule of reason to the facts as found by the Commission requires affirming the Commission—just as the Court of Appeals did below.

***782** I

The Commission's conclusion is lawful if its "factual findings," insofar as they are supported by "substantial evidence," "make out a violation of Sherman Act § 1." *FTC v. Indiana Federation of Dentists,* 476 U.S. 447, 454–455, 106 S.Ct. 2009, 90 L.Ed.2d 445 (1986). To determine whether that is so, I would not simply ask whether the restraints at issue are anticompetitive overall. Rather, like the Court of Appeals (and the Commission), I would break that question down into four classical, subsidiary antitrust questions: (1) What is the specific restraint at issue? (2) What are its likely anticompetitive effects? (3) Are there offsetting procompetitive justifications? (4) Do the parties have sufficient market power to make a difference?

A

The most important question is the first: What are the specific restraints at issue? See, *e.g., National Collegiate Athletic Assn. v. Board of Regents of Univ. of Okla.,* 468 U.S. 85, 98–100, 104 S.Ct. 2948, 82 L.Ed.2d 70 (1984) (*NCAA*); *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.,* 441 U.S. 1, 21–23, 99 S.Ct. 1551, 60 L.Ed.2d 1 (1979). Those restraints do *not* include merely the agreement to which the California Dental Association's (Dental Association or Association) ethical rule literally refers, namely, a promise to refrain from advertising that is " 'false or misleading in

any material respect.' " *Ante,* at 1608 (quoting California Dental Code of Ethics § 10 (1993), App. 33). Instead, the Commission found a set of restraints arising out of the way the Dental Association implemented this innocent-sounding ethical rule in practice, through advisory opinions, guidelines, enforcement policies, and review of membership applications. *In re California Dental Assn.,* 121 F.T.C. 190 (1996). As implemented, the ethical rule reached beyond its nominal target, to prevent truthful and nondeceptive advertising. In particular, the Commission determined that the rule, in practice:

***783** (1) "precluded advertising that characterized a dentist's fees as being low, reasonable, or affordable," *id.,* at 301;

(2) "precluded advertising ... of across the board discounts," *ibid.;* and

****1619** (3) "prohibit[ed] all quality claims," *id.,* at 308.

Whether the Dental Association's basic rule *as implemented* actually restrained the truthful and nondeceptive advertising of low prices, across-the-board discounts, and quality service are questions of fact. The Administrative Law Judge (ALJ) and the Commission may have found those questions difficult ones. But both the ALJ and the Commission ultimately found against the Dental Association in respect to these facts. And the question for us—whether those agency findings are supported by substantial evidence, see *Indiana Federation, supra,* at 454–455, 106 S.Ct. 2009—is not difficult.

The Court of Appeals referred explicitly to some of the evidence that it found adequate to support the Commission's conclusions. It pointed out, for example, that the Dental Association's "advisory opinions and guidelines indicate that ... descriptions of prices as 'reasonable' or 'low' do not comply" with the Association's rule; that in "numerous cases" the Association "advised members of objections to special offers, senior citizen discounts, and new patient discounts, apparently without regard to their truth"; and that one advisory opinion "expressly states that claims as to the quality of services are inherently likely to be false or misleading," all "without any particular consideration of whether" such statements were "true or false." 128 F.3d 720, 729 (C.A.9 1997).

The Commission itself had before it far more evidence. It referred to instances in which the Association, without regard for the truthfulness of the statements at issue, recommended denial of membership to dentists wishing to advertise, for example, "reasonable fees quoted in advance," "major savings," or "making teeth cleaning ... inexpensive." ***784** 121 F.T.C., at 301. It referred to testimony that "across-the-board discount advertising in literal compliance with the requirements 'would probably take two pages in the telephone book' and '[n]obody is going to really advertise in that fashion.' " *Id.,* at 302. And it pointed to many instances in which the Dental Association suppressed such advertising claims as "we guarantee all dental work for 1 year," "latest in cosmetic dentistry," and "gentle dentistry in a caring environment." *Id.,* at 308–310.

I need not review the evidence further, for this Court has said that "substantial evidence" is a matter for the courts of appeals, and that it "will intervene only in what ought to be the rare instance when the standard appears to have been misapprehended or grossly misapplied." *Universal Camera Corp. v. NLRB,* 340 U.S. 474, 490–491, 71 S.Ct. 456, 95 L.Ed. 456 (1951). I have said enough to make clear that this is not a case warranting our intervention. Consequently, we must decide only the basic legal question whether the three restraints described above unreasonably restrict competition.

B

Do each of the three restrictions mentioned have "the potential for genuine adverse effects on competition"? *Indiana Federation,* 476 U.S., at 460, 106 S.Ct. 2009; 7 P. Areeda, Antitrust Law ¶ 1503a, pp. 372–377 (1986) (hereinafter Areeda). I should have thought that the anticompetitive tendencies of the three restrictions were obvious. An agreement not to advertise that a fee is reasonable, that service is inexpensive, or that a customer will receive a discount makes it more difficult for a dentist to inform customers that he charges a lower price. If the customer does not know about a lower price, he will find it more difficult to buy lower price service. That fact, in turn, makes it less likely that a dentist will obtain more customers by offering lower prices. And that likelihood means that dentists will prove less likely to offer lower prices. But why should I have to spell out the obvious? To ***785** restrain truthful advertising about lower prices is likely to restrict competition in respect to price—"the central nervous system of the economy." *United States v. Socony–Vacuum Oil Co.,* 310 U.S. 150, 226, n. 59, 60 S.Ct. 811, 84 L.Ed. 1129 (1940); cf., *e.g., Bates v. State Bar of Ariz.,* 433 U.S. 350, 364, 97 S.Ct. 2691, 53 L.Ed.2d 810 (1977) (price advertising plays an "indispensable role in the

allocation of resources in a free enterprise system"); ****1620** *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748, 765, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976). The Commission thought this fact sufficient to hold (in the alternative) that the price advertising restrictions were unlawful *per se.* See 121 F.T.C., at 307; cf. *Socony–Vacuum, supra,* at 222–228, 60 S.Ct. 811 (finding agreement among competitors to buy "spot-market oil" unlawful *per se* because of its tendency to restrict price competition). For present purposes, I need not decide whether the Commission was right in applying a *per se* rule. I need only assume a rule of reason applies, and note the serious anticompetitive tendencies of the price advertising restraints.

The restrictions on the advertising of service quality also have serious anticompetitive tendencies. This is not a case of "mere puffing," as the FTC recognized. See 121 F.T.C., at 317–318; cf. *ante,* at 1616. The days of my youth, when the billboards near Emeryville, California, home of AAA baseball's Oakland Oaks, displayed the name of "Painless" Parker, Dentist, are long gone—along with the Oakland Oaks. But some parents may still want to know that a particular dentist makes a point of "gentle care." Others may want to know about 1–year dental work guarantees. To restrict that kind of service quality advertisement is to restrict competition over the quality of service itself, for, unless consumers know, they may not purchase, and dentists may not compete to supply that which will make little difference to the demand for their services. That, at any rate, is the theory of the Sherman Act. And it is rather late in the day for anyone to deny the significant anticompetitive tendencies of an agreement that restricts competition in any legitimate respect, see, *e.g.,* ***786** *Paramount Famous Lasky Corp. v. United States,* 282 U.S. 30, 43, 51 S.Ct. 42, 75 L.Ed. 145 (1930); *United States v. First Nat. Pictures, Inc.,* 282 U.S. 44, 54–55, 51 S.Ct. 45, 75 L.Ed. 151 (1930), let alone one that inhibits customers from learning about the quality of a dentist's service.

Nor did the Commission rely solely on the unobjectionable proposition that a restriction on the ability of dentists to advertise on quality is likely to limit their incentive to compete on quality. Rather, the Commission pointed to record evidence affirmatively establishing that quality-based competition is important to dental consumers in California. 121 F.T.C., at 309–311. Unsurprisingly, these consumers choose dental services based at least in part on "information about the type and quality of service." *Id.,* at 249. Similarly, as the Commission noted, the ALJ credited testimony to the effect that "advertising the comfort of services will 'absolutely' bring in more patients," and, conversely, that restraining the ability to advertise based on quality would decrease the number of patients that a dentist could attract. *Id.,* at 310. Finally, the Commission looked to the testimony of dentists who themselves had suffered adverse effects on their business when forced by petitioner to discontinue advertising quality of care. See *id.,* at 310–311.

The FTC found that the price advertising restrictions amounted to a "naked attempt to eliminate price competition." *Id.,* at 300. It found that the service quality advertising restrictions "deprive consumers of information they value and of healthy competition for their patronage." *Id.,* at 311. It added that the "anticompetitive nature of these restrictions" was "plain." *Ibid.* The Court of Appeals agreed. I do not believe it possible to deny the anticompetitive tendencies I have mentioned.

C

We must also ask whether, despite their anticompetitive tendencies, these restrictions might be justified by other procompetitive tendencies or redeeming virtues. See 7 Areeda, ***787** ¶ 1504, at 377–383. This is a closer question —at least in theory. The Dental Association argues that the three relevant restrictions are inextricably tied to a legitimate Association effort to restrict false or misleading advertising. The Association, the argument goes, had to prevent dentists from engaging in the kind of truthful, nondeceptive advertising that it banned in order effectively to stop dentists from making unverifiable claims about price or service quality, which claims would mislead the consumer.

The problem with this or any similar argument is an empirical one. Notwithstanding ****1621** its theoretical plausibility, the record does not bear out such a claim. The Commission, which is expert in the area of false and misleading advertising, was uncertain whether petitioner had even *made* the claim. It characterized petitioner's efficiencies argument as rooted in the (unproved) factual assertion that its ethical rule "challenges *only* advertising that is false or misleading." 121 F.T.C., at 316 (emphasis added). Regardless, the Court of Appeals wrote, in respect to the price restrictions, that "the record provides no evidence that the rule has in fact led to increased disclosure and transparency of dental pricing." 128 F.3d, at 728. With respect to quality advertising, the Commission stressed that the Association "offered no convincing argument, let alone evidence, that consumers

of dental services have been, or are likely to be, harmed by the broad categories of advertising it restricts." 121 F.T.C., at 319. Nor did the Court of Appeals think that the Association's unsubstantiated contention that "claims about quality are inherently unverifiable and therefore misleading" could "justify banning all quality claims without regard to whether they are, in fact, false or misleading." 128 F.3d, at 728.

With one exception, my own review of the record reveals no significant evidentiary support for the proposition that the Association's members must agree to ban truthful price and quality advertising in order to stop untruthful claims. The one exception is the obvious fact that one can stop untruthful ***788** advertising if one prohibits all advertising. But since the Association made virtually no effort to sift the false from the true, see 121 F.T.C., at 316–317, that fact does not make out a valid antitrust defense. See *NCAA,* 468 U.S., at 119, 104 S.Ct. 2948; 7 Areeda, ¶ 1505, at 383–384.

In the usual Sherman Act § 1 case, the defendant bears the burden of establishing a procompetitive justification. See *National Soc. of Professional Engineers v. United States,* 435 U.S. 679, 695, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978); 7 Areeda, ¶ 1507b, at 397; 11 H. Hovenkamp, Antitrust Law ¶ 1914c, pp. 313–315 (1998); see also *Law v. National Collegiate Athletic Assn.,* 134 F.3d 1010, 1019 (C.A.10), cert. denied, 525 U.S. 822, 119 S.Ct. 65, 142 L.Ed.2d 51 (1998); *United States v. Brown Univ.,* 5 F.3d 658, 669 (C.A.3 1993); *Capital Imaging Associates v. Mohawk Valley Medical Associates, Inc.,* 996 F.2d 537, 543 (C.A.2), cert. denied, 510 U.S. 947, 114 S.Ct. 388, 126 L.Ed.2d 337 (1993); *Kreuzer v. American Academy of Periodontology,* 735 F.2d 1479, 1492–1495 (C.A.D.C.1984). And the Court of Appeals was correct when it concluded that no such justification had been established here.

D

I shall assume that the Commission must prove one additional circumstance, namely, that the Association's restraints would likely have made a real difference in the marketplace. See 7 Areeda, ¶ 1503, at 376–377. The Commission, disagreeing with the ALJ on this single point, found that the Association did possess enough market power to make a difference. In at least one region of California, the mid-peninsula, its members accounted for more than 90% of the market place; on average they accounted for 75%. See 121 F.T.C., at 314. In addition, entry by new dentists into the market place is fairly difficult. Dental education is expensive (leaving graduates of dental school with $50,000–$100,000 of debt), as is opening a new dentistry office (which costs $75,000–$100,000). *Id.,* at 315–316. And Dental Association members believe membership in the Association is ***789** important and valuable and recognized as such by the public. *Id.,* at 312–313, 315–316.

These facts, in the Court of Appeals' view, were sufficient to show "enough market power to harm competition through [the Association's] standard setting in the area of advertising." 128 F.3d, at 730. And that conclusion is correct. Restrictions on advertising price discounts in Palo Alto may make a difference because potential patients may not respond readily to discount advertising by the handful (10%) of dentists who are not members of the Association. And that fact, in turn, means that the remaining 90% will prove less likely to engage in price competition. Facts such as these have previously led this Court to find market power—unless the defendant has overcome the showing ****1622** with strong contrary evidence. See, *e.g., Indiana Federation,* 476 U.S., at 456–457, 106 S.Ct. 2009; cf. *United States v. Loew's Inc.,* 371 U.S. 38, 45, 83 S.Ct. 97, 9 L.Ed.2d 11 (1962); *Brown Shoe Co. v. United States,* 370 U.S. 294, 341–344, 82 S.Ct. 1502, 8 L.Ed.2d 510 (1962); accord, *United States v. Aluminum Co. of America,* 148 F.2d 416, 424 (C.A.2 1945). I can find no reason for departing from that precedent here.

II

In the Court's view, the legal analysis conducted by the Court of Appeals was insufficient, and the Court remands the case for a more thorough application of the rule of reason. But in what way did the Court of Appeals fail? I find the Court's answers to this question unsatisfactory—when one divides the overall Sherman Act question into its traditional component parts and adheres to traditional judicial practice for allocating the burdens of persuasion in an antitrust case.

Did the Court of Appeals misconceive the anticompetitive tendencies of the restrictions? After all, the object of the rule of reason is to separate those restraints that "may suppress or even destroy competition" from those that "merely regulat[e] and perhaps thereby promot[e] competition." ***790** *Board of Trade of Chicago v. United States,* 246 U.S. 231, 238, 38 S.Ct. 242, 62 L.Ed. 683 (1918). The majority says that

the Association's "advertising restrictions might plausibly be thought to have a net procompetitive effect, or possibly no effect at all on competition." *Ante,* at 1613. It adds that

> "advertising restrictions arguably protecting patients from misleading or irrelevant advertising call for more than cursory treatment as obviously comparable to classic horizontal agreements to limit output or price competition." *Ante,* at 1614.

And it criticizes the Court of Appeals for failing to recognize that "the restrictions at issue here are very far from a total ban on price or discount advertising" and that "the particular restrictions on professional advertising could have different effects from those 'normally' found in the commercial world, even to the point of promoting competition...." *Ibid.*

The problem with these statements is that the Court of Appeals did consider the relevant differences. It *rejected* the legal "treatment" customarily applied "to classic horizontal agreements to limit output or price competition"—*i.e.,* the FTC's (alternative) *per se* approach. See 128 F.3d, at 726–727. It did so because the Association's "policies do not, on their face, ban truthful nondeceptive ads"; instead, they "have been enforced in a way that restricts truthful advertising," *id.,* at 727. It added that "[t]he value of restricting false advertising ... counsels some caution in attacking rules that purport to do so but merely sweep too broadly." *Ibid.*

Did the Court of Appeals misunderstand the nature of an anticompetitive effect? The Court says:

> "If quality advertising actually induces some patients to obtain more care than they would in its absence, then restricting such advertising would reduce the demand for dental services, not the supply; and ... the producers' supply ... is normally relevant in determining ***791** whether a ... limitation has the anticompetitive effect of artificially raising prices." *Ante,* at 1616.

But if the Court means this statement as an argument against the anticompetitive tendencies that flow from an agreement not to advertise service quality, I believe it is the majority, and not the Court of Appeals, that is mistaken. An agreement not to advertise, say, "gentle care" is anticompetitive because it imposes an artificial barrier against each dentist's independent decision to advertise gentle care. That barrier, in turn, tends to inhibit those dentists who want to supply gentle care from getting together with those customers who want to buy gentle care. See P. Areeda & H. Hovenkamp, Antitrust Law ¶ 1505′, p. 404 (Supp.1998). There is adequate reason to believe that tendency present in this case. See *supra,* at 1620.

Did the Court of Appeals inadequately consider possible procompetitive justifications? The Court seems to think so, for it says:

> ****1623** "[T]he [Association's] rule appears to reflect the prediction that any costs to competition associated with the elimination of across-the-board advertising will be outweighed by gains to consumer information (and hence competition) created by discount advertising that is exact, accurate, and more easily verifiable (at least by regulators)." *Ante,* at 1615.

That may or may not be an accurate assessment of the Association's motives in adopting its rule, but it is of limited relevance. Cf. *Board of Trade of Chicago, supra,* at 238. The basic question is whether this, or some other, theoretically redeeming virtue in fact offsets the restrictions' anticompetitive effects in this case. Both court and Commission adequately answered that question.

The Commission found that the defendant did not make the necessary showing that a redeeming virtue existed in practice. See 121 F.T.C., at 319–320. The Court of Appeals, ***792** asking whether the rules, as enforced, "augment [ed] competition and increase[d] market efficiency," found the Commission's conclusion supported by substantial evidence. 128 F.3d, at 728. That is why the court said that "the record provides no evidence that the rule has in fact led to increased disclosure and transparency of dental pricing"—which is to say that the record provides no evidence that the effects, though anticompetitive, are nonetheless redeemed or justified. *Ibid.*

The majority correctly points out that "petitioner alone would have had the incentive to introduce such evidence" of procompetitive justification. *Ante,* at 1615. (Indeed, that is one of the reasons defendants normally bear the burden of persuasion about redeeming virtues. See *supra,* at 1621.) But despite this incentive, petitioner's brief in this Court offers nothing concrete to counter the Commission's conclusion that the record does not support the claim of justification. Petitioner's failure to produce such evidence itself "explain[s] why [the lower court] gave no weight to the ... suggestion that restricting difficult-to-verify claims about quality or patient comfort would have a procompetitive effect by preventing misleading or false claims that distort the market." *Ante,* at 1616.

With respect to the restraint on advertising across-the-board discounts, the majority summarizes its concerns as follows: "Assuming that the record in fact supports the conclusion that the [Association's] disclosure rules essentially bar advertisement of [such] discounts, it does not obviously follow that such a ban would have a net anticompetitive effect here." *Ante,* at 1614. I accept, rather than assume, the premise: The FTC found that the disclosure rules did bar advertisement of across-the-board discounts, and that finding is supported by substantial evidence. See *supra,* at 1619. And I accept as *literally* true the conclusion that the Court says follows from that premise, namely, that "net anticompetitive effects" do not "*obviously* " follow from that ***793** premise. But obviousness is not the point. With respect to any of the three restraints found by the Commission, whether "net anticompetitive effects" follow is a matter of how the Commission, and, here, the Court of Appeals, have answered the questions I laid out at the beginning. See *supra,* at 1618. Has the Commission shown that the restriction has anticompetitive tendencies? It has. Has the Association nonetheless shown offsetting virtues? It has not. Has the Commission shown market power sufficient for it to believe that the restrictions will likely make a real world difference? It has.

The upshot, in my view, is that the Court of Appeals, applying ordinary antitrust principles, reached an unexceptional conclusion. It is the same legal conclusion that this Court itself reached in *Indiana Federation*—a much closer case than this one. There the Court found that an agreement by dentists not to submit dental X rays to insurers violated the rule of reason. The anticompetitive tendency of that agreement was to reduce competition among dentists in respect to their willingness to submit X rays to insurers, see 476 U.S., at 456, 106 S.Ct. 2009—a matter in respect to which consumers are relatively indifferent, as compared to advertising of price discounts and service quality, the matters at issue here. The redeeming virtue in *Indiana Federation* was the alleged ****1624** undesirability of having insurers consider a range of matters when deciding whether treatment was justified—a virtue no less plausible, and no less proved, than the virtue offered here. See *id.,* at 462–464, 106 S.Ct. 2009. The "power" of the dentists to enforce their agreement was no greater than that at issue here (control of 75% to 90% of the relevant markets). See *id.,* at 460, 106 S.Ct. 2009. It is difficult to see how the two cases can be reconciled.

* * *

I would note that the form of analysis I have followed is not rigid; it admits of some variation according to the circumstances. The important point, however, is that its allocation ***794** of the burdens of persuasion reflects a gradual evolution within the courts over a period of many years. That evolution represents an effort carefully to blend the procompetitive objectives of the law of antitrust with administrative necessity. It represents a considerable advance, both from the days when the Commission had to present and/or refute every possible fact and theory, and from antitrust theories so abbreviated as to prevent proper analysis. The former prevented cases from ever reaching a conclusion, cf. Bok, Section 7 of the Clayton Act and the Merging of Law and Economics, 74 Harv. L.Rev. 226, 266 (1960), and the latter called forth the criticism that the "Government always wins," *United States v. Von's Grocery Co.,* 384 U.S. 270, 301, 86 S.Ct. 1478, 16 L.Ed.2d 555 (1966) (Stewart, J., dissenting). I hope that this case does not represent an abandonment of that basic, and important, form of analysis.

For these reasons, I respectfully dissent from Part III of the Court's opinion.

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526 U.S. 756, 119 S.Ct. 1604, 143 L.Ed.2d 935, 67 USLW 3681, 67 USLW 4365, 1999-1 Trade Cases P 72,529, 99 Cal. Daily Op. Serv. 3835, 1999 Daily Journal D.A.R. 4896, 1999 CJ C.A.R. 2910, 12 Fla. L. Weekly Fed. S 262

Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.,* 200 U.S. 321, 337, 26 S.Ct. 282, 50 L.Ed. 499.

1 The advisory opinions, which substantially mirror parts of the California Business and Professions Code, see Cal. Bus. & Prof.Code Ann. §§ 651, 1680 (West 1999), include the following propositions:

"A statement or claim is false or misleading in any material respect when it:

"a. contains a misrepresentation of fact;

"b. is likely to mislead or deceive because in context it makes only a partial disclosure of relevant facts;

"c. is intended or is likely to create false or unjustified expectations of favorable results and/or costs;

"d. relates to fees for specific types of services without fully and specifically disclosing all variables and other relevant factors;

"e. contains other representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

"Any communication or advertisement which refers to the cost of dental services shall be exact, without omissions, and shall make each service clearly identifiable, without the use of such phrases as 'as low as,' 'and up,' 'lowest prices,' or words or phrases of similar import.

> "Any advertisement which refers to the cost of dental services and uses words of comparison or relativity—for example, 'low fees'—must be based on verifiable data substantiating the comparison or statement of relativity. The burden shall be on the dentist who advertises in such terms to establish the accuracy of the comparison or statement of relativity."

"Advertising claims as to the quality of services are not susceptible to measurement or verification; accordingly, such claims are likely to be false or misleading in any material respect." 128 F.3d 720, 723–724 (C.A.9 1997) (some internal quotation marks omitted).

2 The disclosures include:

"1. The dollar amount of the nondiscounted fee for the service[.]

"2. Either the dollar amount of the discount fee or the percentage of the discount for the specific service[.]

"3. The length of time that the discount will be offered[.]

"4. Verifiable fees[.]

"5. [The identity of] [s]pecific groups who qualify for the discount or any other terms and conditions or restrictions for qualifying for the discount." *Id.,* at 724.

3 The FTC Act's prohibition of unfair competition and deceptive acts or practices, 15 U.S.C. § 45(a)(1), overlaps the scope of § 1 of the Sherman Act, 15 U.S.C. § 1, aimed at prohibiting restraint of trade, *FTC v. Indiana Federation of Dentists,* 476 U.S. 447, 454–455, 106 S.Ct. 2009, 90 L.Ed.2d 445 (1986), and the Commission relied upon Sherman Act law in adjudicating this case, *In re California Dental Assn.,* 121 F.T.C. 190, 292, n. 5 (1996).

4 Compare *In re American Medical Assn.,* 94 F.T.C. 701, 983–984, aff'd, 638 F.2d 443 (C.A.2 1980), aff'd. by an equally divided Court, 455 U.S. 676, 102 S.Ct. 1744, 71 L.Ed.2d 546 (1982) *(per curiam),* and *FTC v. National Comm'n on Egg Nutrition,* 517 F.2d 485, 487–488 (C.A.7 1975), with *Community Blood Bank v. FTC,* 405 F.2d 1011, 1017 (C.A.8 1969).

5 Cf. *Bogan v. Hodgkins,* 166 F.3d 509, 514, and n. 6 (C.A.2 1999); *United States v. Brown University,* 5 F.3d 658, 669 (C.A.3 1993); *Chicago Professional Sports Limited Partnership v. National Basketball Assn.,* 961 F.2d 667, 674–676 (C.A.7 1992); *Law v. National Collegiate Athletic Assn.,* 134 F.3d 1010, 1020 (C.A.10 1998); *U.S. Healthcare, Inc. v. Healthsource, Inc.,* 986 F.2d 589, 594–595 (C.A.1 1993).

6 This conclusion is consistent with holdings by a number of Courts of Appeals. In *FTC v. National Comm'n on Egg Nutrition,* the Court of Appeals held that a nonprofit association "organized for the profit of the egg industry," 517 F.2d, at 488, 638 F.2d 443 (C.A.2 1980), fell within the Commission's jurisdiction. In *American Medical Assn. v. FTC,* 638 F.2d 443 (C.A.2 1980), the Court of Appeals held that the "business aspects," *id.,* at 448, of the AMA's activities brought it within the Commission's reach. These cases are consistent with our conclusion that an entity organized to carry on activities that will confer greater than *de minimis* or presumed economic benefits on profit-seeking members certainly falls within the Commission's jurisdiction. In *Community Blood Bank v. FTC,* the Court of Appeals addressed the question whether the Commission had jurisdiction over a blood bank and an association of hospitals. It held that "the question of the jurisdiction over the corporations or other associations involved should be determined on an ad hoc basis," 405 F.2d, at 1018, and that the Commission's jurisdiction extended to "any legal entity without shares of capital which engages in business for profit within the traditional meaning of that language," *ibid.* (emphasis deleted). The Court of Appeals also said that "[a]ccording to a generally accepted definition 'profit' means gain from business or investment over and above expenditures, or gain made on business or investment where both receipts or payments are taken into account," *id.,* at 1017, although in the same breath it noted that the term's "meaning must be derived from the context in which it is used," *id.,* at 1016. Our decision here is fully consistent with *Community Blood Bank,* because the CDA contributes to the profits of at least some of its members, even on a restrictive definition of profit as gain above expenditures. (It should go without saying that the FTC Act does not require for Commission jurisdiction that members of an entity turn a profit on their membership, but only that the entity be organized to carry on business for members' profit.) Nonetheless, we do not, and indeed, on the facts here, could not, decide today whether the Commission has jurisdiction over nonprofit organizations that do not confer profit on for-profit members but do, for example, show annual income surpluses, engage in significant commerce, or compete in relevant markets with for-profit players. We therefore do not foreclose the possibility that various paradigms of profit might fall within the ambit of the FTC Act. Nor do we decide whether a purpose of contributing to profit only in a presumed sense, as by enhancing professional educational efforts, would implicate the Commission's jurisdiction.

7 A letter from Bureau of Corporations Commissioner Joseph E. Davies to Senator Francis G. Newlands, the bill's sponsor and a member of the Conference Committee, written August 8, 1914, before the Conference Committee revisions, included a memorandum dated August 7, 1914, that expressed concern that the versions of the bill passed by the House and the Senate would not extend jurisdiction to purportedly nonprofit organizations, which might "furnish convenient vehicles for common understandings looking to the limitation of output and the fixing of prices contrary to law." Trade Commission Bill: Letter from the Commissioner of Corporations to the Chairman of the Senate Comm. on Interstate Commerce, Transmitting Certain Suggestions Relative to the Bill (H.R. 15613) to Create a Federal Trade Commission, 63d Cong., 2d Sess., 3 (1914).

8 We leave to the Court of Appeals the question whether on remand it can effectively assess the Commission's decision for substantial evidence on the record, or whether it must remand to the Commission for a more extensive rule-of-reason analysis on the basis of an enhanced record.

9 That false or misleading advertising has an anticompetitive effect, as that term is customarily used, has been long established. Cf. *FTC v. Algoma Lumber Co.,* 291 U.S. 67, 79–80, 54 S.Ct. 315, 78 L.Ed. 655 (1934) (finding a false advertisement to be unfair competition).

10 "The fact that a restraint operates upon a profession as distinguished from a business is, of course, relevant in determining whether that particular restraint violates the Sherman Act. It would be unrealistic to view the practice of professions as interchangeable with other business activities, and automatically to apply to the professions antitrust concepts which originated in other areas. The public service aspect, and other features of the professions, may require that a particular practice, which could properly be viewed as a violation of the Sherman Act in another context, be treated differently." *Goldfarb v. Virginia State Bar,* 421 U.S. 773, 788–789, n. 17, 95 S.Ct. 2004, 44 L.Ed.2d 572 (1975).

11 Justice BREYER claims that "the Court of Appeals did consider the relevant differences." *Post,* at 1622. But the language he cites says nothing more than that *per se* analysis is inappropriate here and that "some caution" was appropriate where restrictions purported to restrict false advertising, see 128 F.3d, at 726–727. Caution was of course appropriate, but this statement by the Court of Appeals does not constitute a consideration of the possible differences between these and other advertising restrictions.

12 Justice BREYER suggests that our analysis is "of limited relevance," *post,* at 1623, because "the basic question is whether this ... theoretically redeeming virtue in fact offsets the restrictions' anticompetitive effects in this case," *ibid.* He thinks that the Commission and the Court of Appeals "adequately answered that question," *ibid.,* but the absence of any empirical evidence on this point indicates that the question was not answered, merely avoided by implicit burden shifting of the kind accepted by Justice BREYER. The point is that before a theoretical claim of anticompetitive effects can justify shifting to a defendant the burden to show empirical evidence of procompetitive effects, as quick-look analysis in effect requires, there must be some indication that the court making the decision has properly identified the theoretical basis for the anticompetitive effects and considered whether the effects actually are anticompetitive. Where, as here, the circumstances of the restriction are somewhat complex, assumption alone will not do.

13 Justice BREYER wonders if we "mea[n] this statement as an argument against the anticompetitive tendencies that flow from an agreement not to advertise service quality." *Post,* at 1622. But as the preceding sentence shows, we intend simply to question the logic of the Court of Appeals's suggestion that the restrictions are anticompetitive because they somehow "affect output," 128 F.3d, at 728, presumably with the intent to raise prices by limiting supply while demand remains constant. We do not mean to deny that an agreement not to advertise service quality might have anticompetitive effects. We merely mean that, absent further analysis of the kind Justice BREYER undertakes, it is not possible to conclude that the net effect of this particular restriction is anticompetitive.

14 The Commission said only that " 'mere puffing' deceives no one and has never been subject to regulation." 121 F.T.C., at 318. The question here, of course, is not whether puffery may be subject to governmental regulation, but whether a professional organization may ban it.

15 Other commentators have expressed similar views. See, *e.g.,* Kolasky, Counterpoint: The Department of Justice's "Stepwise" Approach Imposes Too Heavy a Burden on Parties to Horizontal Agreements, Antitrust 41, 43 (spring 1998) ("[I]n applying the rule of reason, the courts, as with any balancing test, use a sliding scale to determine how much proof to require"); Piraino, Making Sense of the Rule of Reason: A New Standard for Section 1 of the Sherman Act, 47 Vand. L.Rev. 1753, 1771 (1994) ("[C]ourts will have to undertake varying degrees of inquiry depending upon the type of restraint at issue. The legality of certain restraints will be easy to determine because their competitive effects are obvious. Other restrictions will require a more detailed analysis because their competitive impact is more ambiguous"). But see Klein, A "Stepwise" Approach for Analyzing Horizontal Agreements Will Provide a Much Needed Structure for Antitrust Review, Antitrust 41,

42 (spring 1990) (examination of procompetitive justifications "is by no means a full scrutiny of the proffered efficiency justification. It is, rather, a hard look at the justification to determine if it meets the defendant's burden of coming forward with—but not establishing—a valid efficiency justification").

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