UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Nos. 15-3559, 15-3591, 15-3681 & 15-3682

In re Wellbutrin XL Antitrust Litigation

Aetna Healthcare of California Inc. et al.,
Plaintiffs-Appellants

v.

SmithKlineBeecham Corp. et al.,
Defendants-Appellees

On Appeal from the United States District Court
for the Eastern District of Pennsylvania

Case Nos. 08-cv-2431, 08-cv-2433

BRIEF OF THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

Linda E. Kelly
Quentin Riegel
Leland P. Frost
MANUFACTURERS' CENTER FOR LEGAL ACTION
733 10th Street, NW, Suite 700
Washington, DC 20001

Brian H. Pandya*
Amanda L. Lutz
WILEY REIN LLP
1776 K Street NW
Washington, DC 20006
(202) 719-7000
**Counsel of Record*

Attorneys for the National Association of Manufacturers

Date: May 10, 2016

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the undersigned counsel certifies that the National Association of Manufacturers ("NAM") is a nonprofit group. The NAM is America's preeminent manufacturing association and the largest industrial trade group in the United States, representing small and large manufacturers in a wide range of industrial sectors and in all 50 states. The NAM has no parent corporation, and no publicly held company has 10% or greater ownership in the NAM.

Dated: May 10, 2016

/s/ Brian H. Pandya
Brian Pandya

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

TABLE OF AUTHORITIES
(*Continued*)

Page(s)

FEDERAL STATUTES

TABLE OF AUTHORITIES
(*Continued*)

Page(s)

OTHER AUTHORITIES

STATEMENT OF INTEREST OF *AMICUS CURIAE*

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing large and small manufacturers in every industrial sector and in all 50 states. Manufacturing employs nearly 12 million men and women, contributes more than $2.17 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for three-quarters of private-sector research and development. The NAM is a powerful voice for the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

This appeal raises issues of direct concern to the NAM and to American industry as a whole. Members of the NAM are innovators, patent holders, and patent challengers, as well as purchasers and consumers of patented articles and technologies: in other words, voices from every side of patent controversies and from almost every area of the economy. Accordingly, the NAM and its membership have a strong interest in the development of legal rules that enable parties to efficiently resolve disputes, avoid lengthy and burdensome litigation, and focus on the development and commercialization of new technologies.

Pursuant to Fed. R. App. P. 29(a), the NAM states that all parties, including Plaintiffs-Appellants, have consented to the filing of this brief.

Pursuant to Fed. R. App. P. 29(c)(5), the NAM further states that no party or counsel for a party authored this brief in whole or in part. No party or counsel for a party contributed money that was intended to fund preparing or submitting this brief. No person or entity other than the NAM has contributed money that was intended to fund preparing or submitting this brief.

Given the size and breadth of NAM's membership, nearly every case of interest to the U.S manufacturing community directly or indirectly involves one or more NAM members. In such cases, the NAM is not precluded from representing the interests of its entire membership by filing amicus curiae submissions. In particular, no parties to this case provided financial assistance or otherwise participated in the decision-making process for preparing and filing this submission.

SUMMARY OF THE ARGUMENT

FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013), was not meant to create a Catch-22 for patent litigants. Yet that is what will occur if the district court's decision is reversed. Patent challengers would be forced to either launch generic drug products before completing litigation and risk facing substantial monetary damages for patent infringement if a patent is later found valid and infringed, or wait until litigation is complete to launch their products. Patent holders would be forced to either indefinitely continue patent infringement litigation or defend antitrust claims simply for settling patent litigations on mutually beneficial and economically rational terms.

Such outcomes negatively impact patent holders, patent challengers, and consumers by causing lengthier patent litigation that will ultimately delay competing products from entering the market. These outcomes acutely interest the NAM and its members that assert and defend patent infringement claims. Most NAM members also provide healthcare benefits to their employees, so the NAM is concerned with "balanc[ing] the goal of making available more low cost generic drugs . . . with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement." *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp. (In re Lamictal Direct Purchaser Antitrust Litig.*), 791 F.3d 388, 394 (3d Cir. 2015) (internal quotations omitted).

Consistent with these interests, this case provides a model for settling patent infringement lawsuits to minimize litigation and bring generic competition to the market in an orderly and expeditious manner. This case involves a settlement between Biovail Laboratories, Inc. ("Biovail"), the manufacturer and co-promoter of Wellbutrin XL (extended release bupropion hydrochloride), and generic manufacturers Anchen Pharmaceuticals, Inc. ("Anchen") and Anchen's marketing partner Teva Pharmaceuticals USA, Inc. ("Teva").[1] The settlement agreement allowed generic competition before the completion of litigation and without the generic drug manufacturer incurring the danger of an at-risk launch.

Contrary to the speculative allegations of Plaintiffs-Appellants ("Plaintiffs"), the settlement agreement did not, as a practical matter, delay Teva/Anchen in bringing to market generic extended release bupropion hydrochloride. Rather, the agreement guaranteed a generic version of Wellbutrin XL would enter the market on the *earlier* of an agreed upon date or the Federal Circuit affirming a district court's judgment of non-infringement in favor of Anchen. As it turned out, Teva/Anchen launched their generic product *before* the Federal Circuit rendered its decision.

[1] An entity of Defendants-Appellees SmithKline Beecham Corporation d/b/a GlaxoSmithKline LLC and GlaxoSmithKline plc (collectively hereafter "GSK") was the other co-promoter of Wellbutrin XL.

This is the type of settlement that should be commended under *Actavis*, not subjected to antitrust condemnation. *See* 133 S. Ct. at 2234 ("We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit."). Absent this agreement, Teva/Anchen either would have been forced to launch at risk while awaiting a Federal Circuit decision and face crippling damages if later found liable for patent infringement, or stay off the market until the Federal Circuit rendered a favorable decision and the threat of liability passed.

The settlement agreement also includes routine terms found in license agreements entered by manufacturers of all varieties. Biovail granted Teva a patent license for a limited period of time. The parties agreed to a limited window where Biovail could pursue an appeal at the Federal Circuit and then forgo—only at the moment of generic market entry—the expense of continued patent litigation. The district court's well-reasoned opinion should be affirmed so as not to impede the future ability of manufacturers to settle complex patent litigation on flexible and creative terms.

ARGUMENT

I. An Agreement That Preserves Pending Patent Litigation and Enables Generic Competition Is Procompetitive

Plaintiffs build their antitrust case on the remarkable notion that absent the challenged settlement agreement, Teva/Anchen would have made the economically

risky decision to launch their generic product while two separate patent litigations, the lawsuit instituted by Biovail and a separate patent lawsuit instituted by Andrx Pharmaceuticals, were still pending. These allegations are too speculative to give rise to a valid antitrust claim. Allowing an antitrust case to proceed under Plaintiffs' theories will harm both branded and generic pharmaceutical manufacturers and their consumers.

Antitrust plaintiffs should be required to present facts demonstrating what actually would have happened absent the challenged settlement agreement. The timeline and facts of this case do not support the assertion that Teva/Anchen necessarily would have launched a generic drug product earlier than they did under the settlement agreement. Absent the settlement agreement, Teva/Anchen would have waited at least until a decision on a preliminary injunction in the Andrx patent litigation. And they could have waited until the Federal Circuit resolved GSK's appeal to launch their generic product. The district court correctly rejected Plaintiffs' speculative claims.

The timeline of this case is critical.[2] The underlying patent infringement litigation began in November 2004. *See Biovail Labs. Inc. v. Anchen Pharms. Inc.*, Case No. 8:04-cv-01468-JVS-RC (C.D. Cal.). After a claim construction order

[2] Except as noted otherwise, all factual assertions are taken from the district court's memorandum opinion granting summary judgment. *See* Case 2:08-cv-02431-MAM, D.I. 612 (E.D. Pa. Sept. 23, 2015) (hereafter "2015 Slip Op.").

issued in February 2006, Anchen moved for summary judgment of non-infringement. The district court initially indicated it would deny Anchen's motion but later changed course and granted the motion in August 2006. Biovail appealed this decision to the Federal Circuit in September 2006. The FDA approved Anchen's Abbreviated New Drug Application ("ANDA") in December 2006. At this point, Teva/Anchen had regulatory approval to launch their generic product, but any launch would have been "at risk" in view of the pending Federal Circuit appeal, as well as the pending Andrx litigation. The Federal Circuit conducted oral argument in September 2007 and had not issued a decision when the appeal was dismissed in June 2008.

Biovail and Teva/Anchen executed the settlement agreement at issue in February 2007. That agreement provided that Teva/Anchen would launch their generic product at the *earlier* of either May 30, 2008, or a decision by the Federal Circuit affirming the grant of summary judgment of non-infringement. The agreed-upon back-end launch date, May 30, 2008, arrived before the Federal Circuit rendered a decision in the pending appeal, meaning that absent this agreement any launch would have been at risk. While it is possible that Teva/Anchen *might* have launched at risk, it is also possible that Teva/Anchen *might not* have launched their generic product until sometime after May 2008, fearing an award of damages if the Federal Circuit reversed the district court's

judgment of non-infringement. Teva/Anchen also *might not* have launched at all if Andrx had succeeded in obtaining a preliminary injunction, but that risk was taken off the table by the settlement agreement providing Teva/Anchen with a sublicense to Andrx's patent. A plaintiff alleging an antitrust violation should be required to present clear evidence of delayed market entry, not speculative claims where multiple market entry dates are plausible.

This case does not present the pernicious situation of a patent holder paying a patent challenger to drop an invalidity challenge and remain off the market. The underlying patent litigation was still pending at the Federal Circuit when Teva/Anchen entered the market in May 2008. The settlement agreement provided licenses to both Biovail's patent and the patent owned by Andrx, a company that was separately suing Anchen and thus creating an additional barrier to generic competition. If this Court accepts Plaintiffs' arguments, drug manufacturers like Teva and Anchen would be forced to choose between launching at-risk or continuing patent litigation and accordingly delaying product launches. Neither option is attractive to manufacturers, and some manufacturers would choose the latter option, to the detriment of consumers.

The settlement agreement in this case provided orderly mechanisms for Teva/Anchen to bring their generic drugs to market without an at-risk launch *and* for the parties to continue the patent litigation until the backend generic entry date.

Without this agreement, Teva/Anchen may have been precluded by the Andrx patent litigation from entering the market and, even if not precluded by an injunction, may have declined to enter at risk of both the Andrx and Biovail litigations. Notably, as of the date Teva/Anchen entered the market in May 2008, the Federal Circuit had not resolved the pending appeal in favor of Anchen.

Plaintiffs understate the danger of at-risk launches to advance their argument that Teva/Anchen was paid to delay launching. Many manufacturers are reluctant to launch at risk given the uncertainty of patent litigation. Indeed, because patent cases are inherently complex and tend to raise questions of law subject to *de novo* review, nearly half of all appealed district court judgments in patent cases are reversed by the Federal Circuit, which has exclusive jurisdiction over patent appeals. *See* PricewaterhouseCoopers, *2015 Patent Litigation Study* 21 (May 2015), http://www.pwc.com/us/en/forensic-services/publications/assets/2015-pwc-patent-litigation-study.pdf ("roughly equal portions of appealed cases are affirmed in total (48%) as are modified in some regard (52%)"). The possibility of reversal was particularly pronounced in this case, as the two principal issues on appeal—the grant of summary judgment of non-infringement and the claim construction of the asserted patent—are both subject to *de novo* review. *See Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570 (Fed. Cir. 1995) (review of summary judgment); *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) (claim construction

is a question of law); *but cf. Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841-42 (2015) (subsidiary factual findings integral to claim construction sometimes entitled to deference on review).

In cases where a drug company launches at risk only to be later found liable for patent infringement, damages awards can be substantial, as the drug company that launched at risk must either pay the lost profits of the patent holder or pay a double-digit royalty rate. *See* 35 U.S.C. § 284; s*ee AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1333-35 (Fed. Cir. 2015) (affirming the district court awarding a 50% royalty rate). Enhanced damages for willful infringement are also possible in at-risk launches. *See Signtech USA, Ltd. v. Vutek, Inc.*, 174 F.3d 1352, 1358-59 (Fed. Cir. 1999). Some courts have even ordered injunctive relief requiring generic manufacturers to recall products launched at risk. *E.g., Randall May Int'l, Inc. v. DEG Music Prods., Inc.*, No. 2009-1367, 2009 WL 2355838, at *1 (Fed. Cir. July 30, 2009); *Ortho McNeil Pharm., Inc. v. Barr Labs., Inc.*, No. 03-4678 (SRC), 2009 WL 2182665, at *11 (D.N.J. July 22, 2009). For these reasons, it is not surprising that generic drug companies do not routinely undertake at-risk launches. Plaintiffs' allegations that Teva/Anchen would have voluntarily launched at risk in this case are too disconnected from the economic realities of

pharmaceutical manufacturing to give rise to antitrust scrutiny.[3] This Court should affirm the dismissal of Plaintiffs' claims.

Additionally, even if Plaintiffs did articulate specific facts that warranted allowing their antitrust claims to proceed, taking away the ability of manufacturers to enter into settlement agreements such as the agreement in this case that avoided an at-risk launch while facilitating generic market entry before the conclusion of litigation will harm manufacturers and consumers. Patent holders and challengers would both be forced to incur the time and expense of prolonged patent litigation, which as explained below is extraordinarily expensive and uncertain. The fear of damages associated with an at-risk launch would cause generic manufacturers to voluntarily forgo entering the market until that patent litigation is resolved, to the ultimate detriment of consumers.

II. What Plaintiffs Characterize As GSK's No-Authorized Generic Promise Is Nothing More Than a Patent License

Plaintiffs cast aspersions on GSK agreeing not to launch an authorized generic product—dubbed the "no-AG" provision—for a limited period after

[3] If Plaintiffs' allegations are correct that the settlement agreement represented an in-kind transfer of $200 million from Biovail or GSK to Teva/Anchen (and the NAM takes no position on the veracity of these allegations), Teva/Anchen could face treble damages of up to $600 million if the Federal Circuit reversed the judgment of non-infringement and Teva/Anchen were found to infringe GSK's patents, along with the associated costs of a product recall. Plaintiffs' allegations thus actually suggest that economically rational actors such as Teva and Anchen would have declined to enter the market absent this settlement agreement.

Teva/Anchen launched their generic product. Plaintiffs, however, overlook that this was a complex case where both sides stood to gain and lose. It is simply not realistic to assert that Biovail "was always able to settle the infringement suit against Anchen by dismissing the case." *See* Pl. Br. at 67. If walking away was the only way to settle litigation, parties would be disinclined to settle patent litigations, fearing antitrust condemnation.

Plaintiffs' attempt to recast the no-AG provision into a payment to delay Teva/Anchen's market entry thus glosses over the complexities of this case and the need to allow manufacturers to enter into sophisticated settlement agreements. Taking away this tool will make settling cases more difficult. Fewer settlements will ultimately mean less competition as manufacturers forego launching at risk for the reasons discussed above.

The no-AG provision is nothing more than a routine patent license agreement. As the patent holder, Biovail holds the right to exclude all others in the United States from making a product that embodied its patent. 35 U.S.C. § 271. Biovail also holds the right to "grant and convey an exclusive right under [its] patents, to the whole or any specified part of the United States." 35 U.S.C. § 261. The granting of an exclusive license is legal under the patent laws, and choosing to do so cannot subject parties to antitrust scrutiny.

Here, Biovail granted Teva/Anchen the right to sell extended release bupropion hydrochloride tablets that directly competed with GSK's Wellbutrin XL product. The license was exclusive to Teva/Anchen vis-à-vis the other generic manufacturers in the underlying patent infringement lawsuit in that it provided that Teva/Anchen would be the sole generic manufacturer selling a licensed product for a period of time. The license, however, permitted more competition than many exclusive licenses by allowing Teva/Anchen to sell a generic drug while GSK sold the branded drug. This arrangement benefitted customers by enabling generic competition that otherwise did not exist.

Subjecting routine license agreements to antitrust scrutiny would harm consumers—who receive access to more choices and competing products when manufacturers license their patents—and the manufacturing sector—which depends on exclusive licenses to protect and commercialize technology. One study found that exclusive licenses represent 66% of all patent licenses issued by commercial licensors. *See* Thomas R. Varner, *An Economic Perspective on Patent Licensing Structure and Provisions*, 46 BUS. ECON. 229, 237 (2011). In the life sciences sector, that figure jumps to 84%. *Id*. This Court should not allow Plaintiffs to turn routine patent licensing practices into antitrust claims.

Exclusive licenses, or partly exclusive licenses, are popular because of their pro-competitive effects. Those effects include "promot[ing] competition among

suppliers by providing an incentive to maximize the number of programs offered and by maximizing the supplier's revenues from the licenses," and "encourage[ing] additional licensee commitment . . . and improvements in product design, quality, distribution, and coordination." *See Ralph C. Wilson Indus., Inc. v. Am. Broad. Cos. Inc.*, 598 F. Supp. 694, 706 (N.D. Cal. 1984); *Am. Needle, Inc. v. New Orleans La. Saints*, Case No. 04-cv-7806, 2014 WL 1364022, at *1 (N.D. Ill. Apr. 7, 2014).

Those recognized benefits were achieved in this case. Teva/Anchen's licensed market entry meant more companies than just GSK were making and selling extended release bupropion hydrochloride tablets and gave consumers a choice of manufacturers. For these additional reasons, the district court judgment should be affirmed.

III. The Court Should Encourage Flexibility in Patent Settlements

Given the cost and complexity of patent litigation, the Court should encourage settlements and not allow speculative antitrust complaints to deter settlement. Plaintiffs' desire to scrutinize the Wellbutrin settlement on a term-by-term basis rather than on the totality of the integrated agreement will make patent cases harder to settle by removing the flexibility and creativity that parties often require to reach an appropriate settlement agreement.

A. Patent Cases Are Extraordinarily Costly and Complex

Manufacturers that find themselves in patent litigation know firsthand the cost and complexity of patent litigation. As the Federal Circuit observed, "an average patent case cost[s] upwards of $3 million for each side." *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 629 F.3d 1374, 1376-77 (Fed. Cir. 2011) (Moore, J., concurring). The median patent litigation costs are no better than the average costs, with even small cases costing $1 million to litigate from start to finish, according to the American Intellectual Property Law Association's annual survey of patent litigation economics:

Amount in controversy	**Fees/Costs Through End of Discovery**	**Total Fees/Costs**
< $1.0 million	$400,000	$600,000
$1.0 -- $10.0 million	$950,000	$2,500,000
$10.0 -- $25.0 million	$1,900,000	$3,100,000
>$25.0 million	$3,000,000	$5,000,000

See American Intellectual Property Law Association (AIPLA), 2015 *Report of the Economic Survey*, 3. Most pharmaceutical cases, such as the underlying patent disputes here, tend to fall into the category of large patent cases, costing upwards of $10 million to litigate. *See* Michael R. Herman, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1795 n.41 (2011).

Other courts have acknowledged this cost and complexity of patent litigation. The Supreme Court observed that "patent litigation is particularly

complex, and particularly costly." *Actavis*, 133 S.Ct. at 2243. One district court tasked with trying a patent case declared "patent litigation . . . the slowest and most expensive litigation in the United States." *DeLaventura v. Columbia Acorn Trust*, 417 F. Supp. 2d 147, 153 n.7 (D. Mass. 2006). For these reasons, "there is a strong public interest in the settlement of patent litigation." *Foster v. Hallco Mfg. Co., Inc*. 947 F.2d 469, 477 (Fed. Cir. 1991). Plaintiffs' antitrust claims should not undermine this strong public interest.

There is also a strong private interest in the settlement of patent cases. Nearly all complex civil litigation is expensive, wasteful, and "less attractive than almost any alternative" form of dispute resolution. *See* Lawyers for Civil Justice *et al*., *Statement on Litigation Cost Survey of Major Companies* (2010) (available at http://www.uscourts.gov/file/document/litigation-cost-survey-major-companies); Hon. Patrick Higginbotham, *The Disappearing Trial and Why We Should Care*, RAND REVIEW 3 (Summer 2004).

Patent litigation, with its "inherent[ ] uncertain[ty]," often embodies the worst of these unattractive characteristics. *See In re Ciproflaxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003). The average patent case runs 2.4 years from filing to trial, with additional required time to resolve appeals—and pharmaceutical cases, such as the cases between Biovail, Andrx, and

Anchen, tend to be large cases that take longer than average to resolve. PricewaterhouseCoopers, *2015 Patent Litigation Study* 14.

Despite investing significant time and expense in patent litigation, many patent litigants feel that when non-technical judges and lay jurors "venture out into the jungle of technology, conflicting expert testimony, technical evidence, and technical arguments" to apply terse patent claim language to complex products, case outcomes are rolls of the dice . *See* Morgan Chu & Joseph M. Lipner, *Adopting A Case Theme,* PATENT LITIGATION STRATEGIES HANDBOOK 41 (Barry L. Grossman & Gary M. Hoffman, eds. 2000). Perhaps for these reasons, 95% of patent cases filed between 1991 and 2011 settled before final judgment on the merits. *See* John W. Schlicher, *Settlement of Patent Litigation and Disputes: Improving Decisions and Agreements to Settle and License* 5 (ABA 2011).

Against this background, this Court should preserve and promote the necessary ability of manufacturers to settle patent cases. Restricting flexibility and creativity makes settling complex patent cases more difficult, as explained below.

B. Given This Complexity, Settlement Agreements Should Be Viewed in Their Totality, Not by Isolated Terms

It is important that settlements in complex cases be viewed in their entirety, as the entirety of the bargain drives settlements. Plaintiffs argue that "GSK and Biovail were always able to settle the infringement suit against Anchen by dismissing the case, and saving all future litigation costs." Pl. Br. at 67. However,

Biovail was under no obligation to surrender their patent infringement claims. If the choices available to parties that wish to settle patent litigation are limited to dismissing a case or continuing to litigate, many parties will continue to litigate. As the Seventh Circuit observed, "[a] negotiation is more likely to be successful when there are several issues to be resolved (integrative bargaining) rather than just one, because it is easier in the former case to strike a deal that will make both parties feel they are getting more from peace than from war." *Duffy Tool & Stamping, LLC v. NLRB*, 233 F.3d 995, 998 (7th Cir. 2000) (internal citations omitted).

The agreement at issue in this case presents a good example of integrative bargaining where the resolution of several issues drove settlement. Biovail had an interest in pursuing its appeal and reversing the judgment of non-infringement to keep generic competition off the market. Teva/Anchen had to balance the interests of prompt market entry with the dangers of an at-risk launch, particularly with the Andrx litigaton also pending. All parties had an interest in minimizing and avoiding the cost and uncertainty of litigation. When these interests are viewed in isolation, "any settlement can be characterized as involving 'compensation' to the defendant, who would not settle unless [it] had something to show for the settlement." *Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).

Settlement, however, was only possible because of the intersection of these interests. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 ("Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary rights [conferred by a patent] through settlement will expose them to [antitrust liability and damages]. . . . This uncertainty . . . would tend to discourage settlement . . . except for those that the patentee is certain to win at trial and the infringer is certain to lose" and vice versa.). If Plaintiffs are allowed to isolate and scrutinize certain provisions, such as the no-AG provision, which were negotiated as the result of the integrative bargaining, settlement would become more difficult. In this case, no settlement might have meant no generic competition to Wellbutrin XL.

The district court also properly relied on undisputed evidence that the no-AG provision was "reasonably necessary" to secure the agreement of one party (Teva) and complete the settling parties' legitimate objectives. *See* 2015 Slip Op. at 62, citing *U.S. v. Brown Univ.*, 5 F.3d 658, 678-79 (3d Cir. 1993). Significantly, that analysis is consistent with the ancillary restraint doctrine first applied by Judge (later Chief Justice) Taft in *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 281 (6th Cir. 1898), *aff'd as modified*, 175 U.S. 211 (1899). *See also Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 227 (D.C. Cir. 1986)

(ancillary restraint is one which is "reasonably necessary" to the overall transaction).

The district court also properly recognized the absence of evidence that the parties, in particular GSK, had acted with anticompetitive intent. The district court noted "the provisions for enhanced [Federal Trade Commission ("FTC")] review" meant that the "FTC was given, in effect, veto power over the Wellbutrin Settlement." (Slip Op. at 66). Thus, "the provisions for enhanced FTC review do tend to negate any anticompetitive aim of the parties, in particular GSK." *Id*. Indeed, the absence of anticompetitive intent by GSK is especially clear given GSK initial unwillingness to sign the settlement agreement without an express finding that that the settlement was "procompetitive." Slip Op. at 25.

In *United States v. Brown Univ.*, 5 F.3d 658, 672 (3d Cir. 1993), this Court recognized that "[w]hile it is well settled that good motives themselves 'will not validate an otherwise anticompetitive practice,' courts often look at intent to help . . . judge the likely effects of challenged activity." Significantly, this Court in *Brown* relied on the seminal opinion of Justice Brandeis in *Board of Trade of City of Chicago v. United States*, 246 U.S. 231, 238 (1918), in which the Supreme Court declared that "knowledge of intent may help the court to interpret facts and to predict consequences" in the context of the Rule of Reason analysis mandated here by *Actavis*. *See also* M.E. Stucke, *Is Intent Relevant?*, 8 J.L. ECON. & POL'Y

801, 817 (2012) ("[The Supreme Court has], since its early formulation of the rule of reason, stated that subjective intent is legally relevant in antitrust cases.").

Here, GSK's express desire for a judicial imprimatur on the issue of competitive effect—as well as the willingness of all signatories to submit the settlement agreement to the FTC's veto power—amount to undisputed proof that the settling parties, and GSK in particular, were not only acting without anticompetitive intent, but were doing everything they could to avoid entering into a settlement with anticompetitive effects. The Court should affirm the district court's rejection of Plaintiffs' antitrust claims.

IV. Conclusion

The Court should affirm the district court's summary judgment dismissal of Plaintiffs' antitrust claims so as not to set precedent that chills future settlements and negatively impacts manufacturers and consumers.

Date: May 10, 2016

/s/ Brian H. Pandya

Linda E. Kelly
Quentin Riegel
Leland P. Frost
MANUFACTURERS' CENTER FOR LEGAL ACTION
733 10th Street, NW, Suite 700
Washington, DC 20001

Brian H. Pandya
Amanda L. Lutz
WILEY REIN LLP
1776 K Street NW
Washington, DC 20006
(202) 719-7000

Counsel for the National Association of Manufacturers

COMBINED CERTIFICATES OF COMPLIANCE AND SERVICE
Case Nos. 15-3559, 15-3591, 15-3681 & 15-3682

BRIEF OF THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

I, hereby, certify that:

1. This brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B). It has 4,580 words as counted by Microsoft Word.

2. The electronic version of this brief is identical to the version sent in hard copy to this Court.

3. The electronic version of this brief is in PDF and was scanned for viruses using Symantec End Point Protection (version 12.1.6). No viruses were found.

4. I filed the electronic version of this brief with the Court using the CM/ECF system. The Notice of Docket Activity generated by CM/ECF constitutes services upon all counsel of record in this case, all of whom have consented to electronic service.

5. I have caused seven (7) copies of this brief to be hand-delivered to the Clerk of Court, United States Court of Appeals for the Third Circuit at 21400 U.S. Courthouse, 601 Market Street, Philadelphia, PA 19106-1790.

6. I am a member of the bar of this Court.

May 10, 2016

/s/ Brian H. Pandya
Brian H. Pandya