In Re: Humira (Adalimumab) Antitrust Litigation

—*Amici on Appeal*—

on appeal to the United States Court of Appeals
for the Seventh Circuit
2020

The following are selections from two amicus briefs filed in the appeal that is pending (as of Spring 2021) of the district court opinion 465 F. Supp. 3d 811 (N.D. Ill. 2020)*, an edited version of which may be found at: http://www.ericejohnson.com/projects/antitrust_materials/docs/In_Re_Humira_(Adalimumab)_Antitrust_Litigation_(section_1_analysis).pdf ("OU/EEJ edit").*

From BRIEF FOR AMICI CURIAE STATES OF WASHINGTON, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, IDAHO, ILLINOIS, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEBRASKA, NEW MEXICO, NEW YORK, NORTH CAROLINA, OREGON, RHODE ISLAND, VIRGINIA, AND WISCONSIN SUPPORTING PLAINTIFFS-APPELLANTS AND REVERSAL (Oct. 13, 2020), available at https://oag.ca.gov/sites/default/files/Humira_States_Amicus.pdf**:**

The district court relied on flawed analyses that—if affirmed—will embolden anticompetitive practices in the pharmaceutical industry and hamstring antitrust enforcers. Its *Actavis* analysis contained three particularly troubling flaws.

First, it held that any agreements granting market entry before patent expiration are automatically immune from antitrust scrutiny. This directly contradicts the Supreme Court's teaching that patent settlements enjoy no presumption of legality. *See FTC v. Actavis*, 570 U.S. 136, 147–48 (2013). The decision below created such a presumption, and did so by resurrecting the discredited "scope of the patent" test. *See In re Humira (Adalimumab) Antitrust Litig.*, No. 19-cv-1873, 2020 WL 3051309, at *{OU/EEJ*

edit at p. 20} (N.D. Il. June 8, 2020) (declaring that AbbVie's Humira agreements at worst "preserved an anticompetitive status quo" created by AbbVie's Humira patents).

Second, it relied on unwarranted factual and legal assumptions about procompetitive effects. The district court announced, for example, that the challenged agreements "deliver value to consumers" and "increased competition." *Id.* at *{OU/EEJ edit at pp. 20 & 21}*. Relying upon disputed facts that contradict the complaint's allegations is improper on a Fed. R. Civ. P. 12(b)(6) motion. Moreover, the challenged agreements caused harm by eliminating the possibility that AbbVie's rivals could enter the U.S. market even earlier than their agreed-upon entry dates. Merely allowing them to enter the U.S. market before AbbVie's disputed patents expired does not eliminate that harm. The district court also assumed without basis that allowing rivals to enter in Europe created cognizable procompetitive effects despite the complaint alleging harm only in the United States.

Third, the district court gave undue weight to the public policy goal of "encouraging patent litigants to settle worldwide patent disputes." *In re Humira,*˜ at *{OU/EEJ edit at pp. 20}*. *Actavis* specifically rejected the argument that any public policy favoring "the desirability of settlements" could trump the application of antitrust law to potentially harmful patent settlements. *Actavis*, 570 U.S. at 158.

In short, the decision below represents a frontal assault on *Actavis* and enforcers' long campaign against anticompetitive conduct in the pharmaceutical industry. Allowing errors like these to persist and gain traction would jeopardize effective antitrust enforcement in this industry while drug prices continue to soar. Amici States urge this Court to correct these errors and reverse the decision below dismissing the Plaintiffs-Appellants' Sherman Act § 1 claims.˜

From AMICI CURIAE BRIEF OF 66 LAW, ECONOMICS, BUSINESS, AND MEDICAL PROFESSORS IN SUPPORT OF PLAINTIFFS-APPELLANTS (Oct. 9, 2020), submitted by Prof. Michael A. Carrier available at https://ssrn.com/abstract=3708338**:**

A company collects more than 100 patents on a drug. It then aggressively asserts this "patent thicket" and enters into settlements with

each of the competitors that could enter the market, paying them to delay their entry for years. The company admits that its strategy is to "make it more difficult" for rivals forced to "contend with [its] extensive patent estate."

Does this violate antitrust law? That presents a nuanced issue. But at least it deserves consideration, which could ultimately involve the weighing of the thicket's benefits against the anticompetitive harms of abusing this collection.

The district court never allowed this critical debate to play out. In particular, it short-circuited the analysis by making fundamental errors on how to (1) analyze settlements, (2) assess sham conduct, and (3) determine causation. These errors require reversal.

Humira is the most advertised drug in the United States. It is used for rheumatoid arthritis, Crohn's disease, colitis, and other serious conditions. Humira is a "biologic," which differs from a small-molecule drug in its complexity and in being produced from living organisms. And it is expensive, costing patients roughly $40,000 a year.

Multiple companies, including Amgen, Boehringer Ingelheim, Fresenius Kabi, Momenta, Mylan, Novartis Sandoz, Pfizer, and Samsung Bioepis developed lower-cost, "biosimilar" versions of Humira. And in 2018, they began to introduce these versions in Europe. The result? Price savings of *as much as 80%*.

Consumers in the United States have not been so lucky. According to the robust allegations in the plaintiffs' complaint, the reason has little to do with innovation or other justifiable business purposes. Instead, it is the result of a sophisticated campaign to obtain "swaths of invalid, unenforceable, or noninfringed patents without regard to the patents' merits." (District court opinion) (citing plaintiffs' complaint). This collection, known as a "patent thicket," can block competition even if many of the patents are invalid or not infringed. The plaintiffs alleged that AbbVie "repeatedly and aggressively assert[ed] this patent thicket during a lengthy, detailed regulatory process (and subsequent infringement litigation)." *Id*.

As a result of this behavior, AbbVie was able to avoid "any real examination of the patents' validity long enough to reap a few more years' worth of monopoly profit." *Id*. This profit—on sales of roughly $20 billion a year—was immensely valuable to AbbVie. It was a windfall for the

biosimilar competitors paid off with some of the bounty. But it was a tragedy for consumers not able to afford treatment.

I. The Court Misapplied the Law on Sham Conduct

In dismissing plaintiffs' allegations, the court's first error was to misapply the law on "sham" conduct.

Under the *Noerr-Pennington* doctrine, "[t]hose who petition [the] government for redress are generally immune from antitrust liability." *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 56 (1993). This doctrine, however, contains a well-established exception for sham conduct, and the Supreme Court has applied the exception to misrepresentations made to courts and administrative agencies.

In its wide-ranging complaint, the plaintiffs alleged a vast array of "bad-faith," sham behavior by AbbVie in "acquir[ing] and assert[ing] whole tracts of questionable patents" in the context of the U.S. Patent and Trademark Office and litigation. In considering this conduct, the court made multiple errors.~

II. The Court Neglected the Severe Harms of Pay-for-Delay Settlements

The district court's second category of errors involves settlements. One of the most collusive forms of anticompetitive behavior in the pharmaceutical industry involves settlements between potential competitors. The setting is straightforward. A brand or biologic company files a patent infringement claim against a generic or biosimilar. The parties settle. Sometimes these settlements violate the antitrust laws because the party with the patent *pays* its potential rival to delay its entry.

In this case, AbbVie filed patent litigation against potential competitors seeking to offer lower-priced biosimilars. Each of the potential rivals settled, agreeing to enter the European market in 2018, but—according to the plaintiffs' allegations, after AbbVie paid them—delaying their entry into the U.S. market until 2023.

A. The Settlements Involved Significant Compensation

The plaintiffs alleged that "early European entry dates were extremely valuable" to the biosimilars. In particular, they contended that AbbVie induced the biosimilars "to delay their U.S. market entry by offering the *quid pro quo* of earlier entry dates in Europe." *Id.* AbbVie's motive "was to keep prices in the U.S. artificially high for as long as

possible." *Id.* This gambit "succeeded." *Id.* The "cost of Humira to treat arthritis in the U.S. [was] 50% more expensive than the cost of the same treatment in Spain (and 155% more expensive than in Switzerland)." *Id.*

The lower court understood this. It acknowledged that "[t]he package deals conferred large European revenue streams (hundreds of millions of dollars . . .) onto the biosimilar companies." The court understood that such payment bought AbbVie even more lucrative monopoly time in the United States that was "worth billions of dollars in revenue." *Id.* And the court conceded that "[t]he settlement terms, when taken together, involve transfers of value from the patentee to the alleged infringer."

In short, the fundamental question posed in *Actavis* of whether the patent holder provided compensation to its potential rival to delay entering the market is straightforward. And it is so clear that the court acknowledged it on multiple occasions. But despite the presence of compensation, the court applied a formalistic analysis inconsistent with *Actavis*.

B. The Court Ignored the Harm from the Settlements

The court found that the settlements did not present concern because they "do not involve a cash payment" and "are of a type specifically permitted by *Actavis*." And again: "[t]hese agreements were decidedly not 'as harmful as those resulting from reverse payments of cash,'" and "it is not unlawful to enter into agreements that have been explicitly recognized by the Supreme Court as not a matter for antitrust concern." (citation omitted).

The court also failed to connect the settlements. It found that the "global patent settlements . . . provided one early entry date for the European market and a different early entry date for the U.S. market—both permissible under *Actavis*." But the court failed to recognize that the combination of settlements in different markets creates the opportunity to hide payment. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 252–53 (3d Cir. 2017) (finding that brand firm could have provided compensation to generic by releasing it from liability in unrelated litigation).

So instead of following its recognition that the settlement transferred "hundreds of millions of dollars" to its natural conclusion that this payment could have led to delayed entry, it created separate boxes

and viewed the settlements as completely independent. The result? The application of the very scope-of-the-patent test rejected in *Actavis*.

In particular, the court concluded that the settlement only involved early entry and that "the effect of the payment was to increase, not restrain, competition by bringing competitors into the market when patents otherwise prohibited the competition." {The court also said} settlements "deliver value to consumers"~. Assuming that "early" entry in a separate market is automatically procompetitive is not consistent with *Actavis* or other cases. *See, e.g.*, *Lipitor*, 868 F.3d at 252 (rejecting settling parties' justification based on generic's "early" entry into second, less lucrative, market). This position ignores the Court's critical holding that "patent *and antitrust* policies are both relevant in determining the 'scope of the patent monopoly.'" 570 U.S. at 148 (emphasis added). In addition, the court's reliance on the policy of encouraging patent settlements belies *Actavis*'s five reasons why the pro-settlement policy was not dispositive. And the court does all of this on a motion to dismiss.

C. *Actavis* Provides the Relevant Framework

The starting point for any analysis of settlements is the Supreme Court's decision in *FTC v. Actavis*, one of the most important antitrust rulings in the past generation. In the decade before *Actavis*, lower courts had immunized settlements by which brand firms paid generics to delay entering the market. These "reverse payment" settlements involve patent-holder brand (or biologic) firms paying potentially infringing generics (or biosimilars) to *delay* entry, which differs from the typical arrangement of alleged infringers paying patentees for licenses to *enter* the market. Courts upheld these settlements (also known as "pay for delay") on several grounds: that they fell within the "scope of the patent," benefited from a presumption of patent validity, were the "natural by-product" of industry legislation, and were supported by the public policy in favor of settlement. *See* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 60–67 (2009) (describing cases). *Actavis*'s importance cannot be overstated. The Court held that reverse-payment settlements have the potential for "significant adverse effects on competition," 570 U.S. at 148, and could "violate the antitrust laws," *id.* at 141.

Actavis's most fundamental underpinning centered on the relationship between patent and antitrust law. Courts before *Actavis* had

upheld reverse-payment settlements as a type of activity falling within the scope of the patent. They reasoned that payment did not "unlawfully extend the reach of the patent" since the patent holder could exclude competition based on the patent itself. In other words, while the patent was still in force, antitrust had no role to play.

Actavis rejected this test. It traced antitrust's robust role in evaluating patent arrangements back to the mid-20th century. *See* 570 U.S. at 147–51. The Court found it "incongruous" to "determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." *Id.* at 148. It made clear that "patent *and antitrust* policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." *Id.* (emphasis added). And it recognized that reverse-payment settlements had the "potential for genuine adverse effects on competition" since "payment in return for staying out of the market . . . keeps prices at patentee-set levels." *Id.* at 154.~

F. *Actavis* Extends to Non-Cash Payments

One issue robustly litigated since *Actavis* is whether payment is limited to cash or extends to other forms of consideration. The Court in *Actavis* recognized that substance, not form, matters, never using the word "cash" and emphasizing that in the challenge to the above-market-value business deal (by which the generic was overpaid for services it provided to the brand), the FTC alleged that, "*in substance*, the plaintiff agreed to pay the defendants many millions of dollars . . . ." *Id.* at 147 (emphasis added).

Can it possibly make economic sense to apply *Actavis* to preclude antitrust scrutiny where, instead of paying cash, the brand pays the generic with some other currency? Or overpays for generic services? Or gives the generic a right to enter a different market (say, one outside the U.S.) worth hundreds of millions of dollars? It does not.

What matters for antitrust analysis is not a transaction's form, but its economic substance. The Supreme Court has consistently required that antitrust analysis "be based upon demonstrable economic effect rather than . . . upon formalistic line drawing." *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 58–59 (1977); *see also Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466–67 (1992) ("formalistic distinctions" are

"generally disfavored in antitrust law"). And that is why the only two appellate courts to consider the issue unanimously rejected the idea that *Actavis* is limited to cash payments. ~ *See* Herbert Hovenkamp et al., IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law § 16.01[D], at 16–39 (2019 Supp.) (citing the "11 district courts [that] have correctly agreed that 'payment' under *Actavis* reaches beyond cash transfers"); *id.* at 16–41 ("the issue of whether payment includes non-cash consideration appears to be resolved"); *cf.* Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for- Delay*, 18 Chi.-Kent J. Intell. Prop. 249, 281 (2019) (noting the "increasing complexity of settlements"). It is no longer legitimate to argue that a payment under *Actavis* must take the specific form of a brand or biologic company paying a generic or biosimilar company in cash.

G. The Third Circuit's *AbbVie* Ruling Supports Reversal

On September 30, 2020, the Third Circuit issued a ruling that provides strong support for reversing the decision below. In that case, the FTC claimed that Abbott paid Teva to delay entering the market with a generic version of testosterone gel AndroGel by providing Teva with a version of cholesterol drug TriCor at "a price that is well below what is customary in such situations." *FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015). In granting the defendants' motion to dismiss, the district court failed to recognize a potential payment, formalistically finding that "the AbbVie Defendants are not making any payments to Teva," but "[i]t is Teva which is paying Abbott for the supply of TriCor." *Id.* The court recognized that "the FTC correctly alleges that something of large value passed from Abbott to Teva," but concluded that "it was not a reverse payment under *Actavis*." *Id.*

The Third Circuit reversed. It explained that because "[t]he purpose of antitrust law is 'to protect consumers from arrangements that prevent competition in the marketplace,' . . . economic realities rather than a formalistic approach must govern." *FTC v. AbbVie Inc.*, 2020 WL 5807873, at *17 (3d Cir. Sept. 30, 2020) (citation omitted). The court also explained that a plaintiff can satisfy pleading standards "without describing in perfect detail the world without the reverse payment, calculating reliably the payment's exact size, or preempting every possible explanation for it." *Id.* The Third Circuit found that the plaintiff cleared this threshold by alleging a "plausibly 'large'" payment in the form of an "extremely

valuable" supply of TriCor anticipated to lead to net sales of "nearly $175 million over a four-year period." *Id.* at *18.~

In conclusion, the Third Circuit offered a roadmap to reversing the decision below. In this case, the plaintiffs alleged that potential biosimilar rivals delayed entering the market and that they received *hundreds of millions of dollars* to do so.

Under any reasonable interpretation of *Actavis*, particularly on a motion to dismiss, this constitutes payment.

III. Antitrust Injury

One issue courts often confront in private litigation is determining whether the plaintiff can show that the defendant's conduct caused its injury. Because the court must determine what would have happened in a counterfactual world, this inquiry presents challenges. Because the plaintiff in *Actavis* was the Federal Trade Commission, which need not demonstrate causation, the Supreme Court did not directly address the issue. But the guidance it provided in its liability assessment supports a flexible—not rigid—causation framework.~

The court applied an overly rigid causation analysis. For starters, it contradicted itself and set inappropriate standards.~

In addition to providing inapt and contradictory standards, the court's ruling is not consistent with *Actavis*. The Supreme Court made clear that the "relevant anticompetitive harm" is the "prevent[ion of] the risk of competition." *Id.* at 157. This applies where there is "even a small risk of invalidity" (in other words, the patent is most likely valid). *Id.* The Court also explained that it is "normally not necessary to litigate patent validity." *Id.* And it looked to "the size of the unexplained reverse payment" as "provid[ing] a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id.* at 158.

It is not consistent with these instructions to require a plaintiff demonstrating antitrust injury to prove precisely what would have happened in a but-for world that, by definition, has not occurred. It directly undermines *Actavis* to assert that "[t]he allegations about what might have happened in the underlying infringement litigation are too speculative and would require legal and factual determinations that go beyond judicially manageable limits." *Id.* at *23.~

Imposing the rigid requirements the court erected would make it nearly impossible for private plaintiffs to win a case under *Actavis*. That would mean that the case has "no practical application except in suits by the government." *In re Aggrenox Antitrust Litig.*, 2015 WL 4459607, at *9 (D. Conn. July 21, 2015).

In short, *Actavis* does not support the high bar the court applied to causation.

CONCLUSION

We request that this Court reverse the decision below, which is built on fundamental errors on the analysis of sham conduct, pay-for-delay settlements, and antitrust injury.

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NOTES ABOUT THE EDITING OF THIS MATERIAL: *The superscript tilde (~) denotes an ellipsis. A few insertions were made with curly brackets. Various citations were removed without notation. Footnotes were eliminated.*