

Back to 2012: The Seventh Circuit's Reliance on Pre-Actavis Law in Dismissing Patent-Thicket Claims

By Michael A. Carrier | Rutgers Law School



Edited by Justin Stewart-Teitelbaum & Angela Landry

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By Michael A. Carrier*

2012 was a long time ago. Barack Obama was in the middle of his two terms as President. Hurricane Sandy swamped the East Coast. The Avengers, The Dark Knight Rises, and The Hunger Games were in the theaters, and Gangnam Style had a billion views on YouTube. For our purposes, in the world of pharmaceutical antitrust law, it was the last year before the Supreme Court’s landmark decision in *FTC v. Actavis*.¹

At that time, courts were engaged in a years-long trend of immunizing settlements by which brand-name drug manufacturers paid generic firms to stay off the market.² These courts concluded that such anticompetitive agreements did not violate antitrust law because they fell within the “scope of the patent” and were justified based on a policy supporting settlements and patent law’s presumption of validity.³

The Court in *Actavis* overturned this analysis, highlighting antitrust’s critical role in assessing patent-based conduct. The Court concluded that “[i]t would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law

policy” rather than by considering “procompetitive antitrust policies as well.”⁴ In the past decade, nearly all of the courts analyzing “reverse payment” settlements have followed the decision.⁵ But in August 2022, the Seventh Circuit, in *Mayor & City Council of Baltimore v. AbbVie Inc.*,⁶ did not, disclaiming a role for antitrust within the scope of the patent. In other words, it’s back to 2012.

Background⁷

The *AbbVie* case involves Humira, an “anti-inflammatory biologic,” which is “a drug derived from living organisms that helps slow down overactive immune systems.”⁸ Originally developed to treat rheumatoid arthritis, Humira “is now used to treat a variety of auto-immune disorders ranging from Crohn’s disease to plaque psoriasis.”⁹ The drug is immensely profitable, “generat[ing] almost \$20 billion in worldwide sales in 2018 alone and more than \$56 billion in the United States between 2012

* Distinguished Professor of Law, Rutgers Law School. Professor Carrier is an authority in antitrust and intellectual property law with expertise in the pharmaceutical industry. He is a co-author of the leading IP/antitrust treatise and the author of more than 130 law review articles and book chapters.

¹ 570 U.S. 136 (2013).

² See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1307 (11th Cir. 2003). In July 2012, the Third Circuit applied the first rigorous analysis since 2003. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) (treating payment from a brand firm to a generic to delay entry as “*prima facie* evidence of an unreasonable restraint of trade”).

³ For additional detail, see Michael A. Carrier, *Eight Reasons Why “No-Authorized-Generic” Promises Constitute Payment*, 67 RUTGERS U.L. REV. 697, 699 (2015).

⁴ 570 U.S. at 148.

⁵ These are called “reverse payments” because the consideration flows from patentee to alleged infringer (unlike typical settlements in which alleged infringers pay patentees).

⁶ 42 F.4th 709 (7th Cir. 2022) (hereinafter *Baltimore v. AbbVie*).

⁷ This section is adapted from Michael A. Carrier, *The U.S. District Court for the Northern District of Illinois Dismisses Antitrust Case Challenging Patent Thicket (Humira)*, CONCURRENCES E-COMPETITIONS (No. 96364, Sept. 2020), <https://www.concurrences.com/en/bulletin/news-issues/june-2020/the-us-district-court-for-the-northern-district-of-illinois-dismisses-antitrust>.

⁸ *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 820 (N.D. Ill. June 8, 2020). Biologics and lower-cost rival biosimilars are more complex than small-molecule brand and generic drugs but threaten similar anticompetitive effects. See Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1 (2018).

⁹ *In re Humira*, 265 F. Supp. 3d at 820.

and 2018,” which made it “the best-selling drug in the country.”¹⁰

In this case, the plaintiffs, indirect purchasers of Humira, claimed that “in the months and years leading up to the expiration of the [patent on the active ingredient], AbbVie created a thicket of intellectual property protection so dense that it prevented would-be challengers from entering the market with cheaper biosimilar alternatives.”¹¹ The plaintiffs also claimed that the defendants “used that intellectual property as leverage during negotiations” to “forc[e] [competitors] to agree to delay their market entry in return for licensing agreements that cut through AbbVie’s patent thicket.”¹²

AbbVie “sought patents on not only the many uses of Humira but also the process for manufacturing it and the ingredients and formulations that [the company] anticipated its competition might seek to employ.”¹³ In fact, “[o]ne estimate suggests that AbbVie filed a total of 247 patent applications related to Humira and obtained 132 patents”¹⁴ More than 90% of the patents “were issued in 2014 or later, despite the fact that Humira was first marketed in 2002.”¹⁵

AbbVie’s executives discussed its patent strategy with investors.¹⁶ In 2014, the company’s CFO “said that AbbVie was ‘obviously not very specific about what’ it was putting into its ‘very robust collection of IP’ because ‘with a product as important and as attractive as Humira, you do everything you can on the IP front to ensure that you’ve protected it the best you can.’”¹⁷ This official added that “the

bulk of AbbVie’s IP strategy was to ‘make it more difficult for a biosimilar to follow behind.’”¹⁸ And “[i]n an email to investors, AbbVie’s CEO noted that market entry for any Humira biosimilars would likely be delayed because patent litigation takes more than four years and at-risk launches are rare.”¹⁹ AbbVie’s motive “was to keep prices in the U.S. artificially high for as long as possible.”²⁰ The strategy “succeeded,” as “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).”²¹

Despite all of this, the district court dismissed the plaintiffs’ claims, and the Seventh Circuit affirmed. There were two primary issues in the case: reverse-payment settlements and sham litigation.

Settlements

The first issue is settlements. The plaintiffs claimed that AbbVie’s settlements with biosimilar rivals violated antitrust law. In *FTC v. Actavis*, the Supreme Court explained that a settlement by which a brand-name drug company paid a generic firm to settle patent litigation and delay entering the market could have “significant adverse effects on competition.”²² In fact, the “size of the unexplained reverse payment can provide 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.”²³

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.* at 822.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.* at 823–24.

¹⁷ *Id.* at 824.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.* at 825.

²¹ *Id.*

²² 570 U.S. at 148.

²³ *Id.* at 158. Offering one potential example, Judge Wood noted in oral argument that AbbVie “g[a]ve up . . . 11 years worth of exclusivity for this money machine called Humira” and asked: “[w]hy isn’t that a signal of tremendous weakness of these extension patents?” Oral Argument, *Mayor & City Council of Baltimore v. AbbVie Inc.*, No. 20-2402 (38:30 to 38:49), http://media.ca7.uscourts.gov/sound/2021/mn.20-2402.20-2402_02_25_2021.mp3.

One issue robustly litigated since *Actavis* is whether payment is limited to cash or extends to noncash conveyances. Courts that have examined the issue have adopted the broader approach—extending the payment to noncash conveyances—with the two district courts that did not do so overturned on appeal.²⁴

In this case, the plaintiffs alleged that AbbVie entered into settlements by which biosimilars received early entry dates in Europe “to delay their U.S. market entry.”²⁵ The district court, however, found that the settlements “do not involve a cash payment” and 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*.”²⁶

The Seventh Circuit agreed, finding that “[i]n the United States AbbVie struck a normal settlement without any payment to the entrants, a settlement of the kind that *Actavis* says is not problematic,” and “[i]n Europe AbbVie and the potential entrants struck the same kind of deal, which is proper for the same reason.”²⁷ The court continued: “[i]n each [settlement,] AbbVie agreed to entry before the last patents expired and didn’t pay anyone to delay entry.”²⁸ It concluded: “[a]s the district judge saw things, 0 + 0 = 0” and “[w]e see this the same way.”²⁹

Formulas like this are not consistent with *Actavis*. Again, courts have made clear that payment can—and typically does—take forms other than cash. In fact, the lower court in this case acknowledged that “[t]he package deals conferred large European revenue streams (hundreds of millions of dollars . . .) onto the biosimilar companies, while buying AbbVie even

more lucrative monopoly time in the U.S. (worth billions of dollars in revenue for AbbVie . . .).”³⁰ Similarly, the district court noted that “[t]he settlement terms, when taken together, involve transfers of value from the patentee to the alleged infringer.”³¹

Neither court, however, stepped back to see how the parties could arrange for payment through a combination of settlements. The plaintiffs alleged that “[t]he early European entry dates were extremely valuable” to the biosimilars, and the district court itself acknowledged that “the alleged value of the European early entry dates . . . might take [the settlement agreement] outside the norm.”³² Nevertheless, the court dismissed the claim.

Appellate courts, in considering “an appeal from an order granting a motion to dismiss,” are supposed to “accept all well-pleaded facts as true and draw all reasonable inferences therefrom in the plaintiffs’ favor.”³³ Although this age-old instruction needs no explanation, the Seventh Circuit drew numerous inferences *against* the moving party on issues like the strength of European patents, the drug’s uses, and the royalties biosimilars might pay to AbbVie.³⁴

In addition, the Seventh Circuit, worrying about issuing a “pathfinder decision,” mischaracterized the case’s uniqueness in the post-*Actavis* caselaw by ignoring the array of non-cash settlements that courts have considered potential payment after *Actavis*.³⁵ Many of these settings offered unique facts while camouflaging payment in ever more obscure ways. For example, courts have addressed potential payment taking the form of:

²⁴ Michael A. Carrier, *The Rule of Reason in the Post-Actavis World*, 2018 COLUM. BUS. L. REV. 25, 41 (2018).

²⁵ *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 825 (N.D. Ill. 2020).

²⁶ *Id.* at 836, 840.

²⁷ *Baltimore v. AbbVie*, 42 F.4th at 715.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *In re Humira*, 465 F. Supp. 3d at 840.

³¹ *Id.* at 842.

³² *Id.* at 825, 841.

³³ *Mashallah, Inc. v. W. Bend Mut. Ins. Co.*, 20 F.4th 311, 317 (7th Cir. 2021). See *AbbVie oral argument*, *supra* note 23 (30:46 to 31:30) (Judge Wood asks AbbVie’s counsel if “we have to accept the facts in [AbbVie’s] light” and says she’s “bothered by the fact that this is 12(b)(6)” given that “[t]his is a very detailed complaint”).

³⁴ *Baltimore v. AbbVie*, 42 F.4th at 715.

³⁵ *Id.*

- a brand's providing its product to the generic,³⁶
- a no-authorized-generic ("no-AG") promise by which a brand promises not to introduce its own generic that would compete with the "true" generic,³⁷
- the combination of a no-AG agreement and a development/co-promotion agreement,³⁸
- a "no third-party AG provision" that "prevents [the brand firm] from distributing an AG through a third party,"³⁹
- an "acceleration clause" by which the brand agrees that the generic "would be permitted to reenter the market . . . earlier than the otherwise agreed-to reentry date" if another generic entered the market,⁴⁰
- a "most-favored entry plus" clause by which the brand agreed not to "grant a license for a second [generic] filer to enter the market any earlier than" a period after the settling first-filing generic entered,⁴¹ and
- a payment from the generic to the brand to forgive potential damages after the generic entered the market for a short time.⁴²

The Seventh Circuit also assumed that the potential for royalty payments showed that the settlement at issue was "one of the traditional kinds squarely protected by *Actavis*."⁴³ But this diverges from other courts that have offered more nuanced analyses. The Third Circuit, for example, rejected a defendant's argument that a settlement "is not subject to antitrust scrutiny because [it] is 'traditional' in that it is justified by [the generic's] payment of royalties to [the

brand]."⁴⁴ The Third Circuit's reasoning is inherent in the standards at the motion-to-dismiss stage: "[a]lthough the royalty licensing provisions will perhaps be a valid defense, they require factual assessments, economic calculations, and expert analysis that are inappropriate at the pleading stage."⁴⁵ Another court similarly observed that "royalty payments may be 'effectively a kickback'" and "may achieve the same effect" as other arrangements recognized to constitute payment.⁴⁶

The Seventh Circuit's ruling stands in contrast not only to courts that have considered royalties but also to courts that have analyzed simultaneous settlements. For example, the Third Circuit concluded that a payment was plausibly alleged when the generic manufacturer paid \$1 million to settle separate litigation involving a drug for which it faced higher potential liability for patent infringement.⁴⁷ And a district court found a potential payment "premised on the value offered by settling another and different lawsuit" based on the plaintiffs' allegation that the combination of the two settlements "produced a reverse payment settlement where defendants overpaid [the generic manufacturer] in the [settlement on the other drug]."⁴⁸ The court in that case found that "the summary judgment facts support a reasonable inference that the parties, . . . by negotiating the two settlements together, . . . traded one settlement generic entry date for another."⁴⁹

The analysis in these cases is consistent with antitrust's preference for a focus on "economic effect rather than . . . formalistic line drawing."⁵⁰

³⁶ *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA (Lidoderm)*, 74 F. Supp. 3d 1052 (N.D. Cal. 2014).

³⁷ *King Drug Company of Florence v. Smithkline Beecham Corp. (Lamictal)*, 791 F.3d 388 (3d Cir. 2015).

³⁸ *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704 (N.D. Ill. 2016).

³⁹ *In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639, 668 (D. Mass. 2020).

⁴⁰ *In re Sensipar Antitrust Litig.*, 2020 WL 7022364 (D. Del. Nov. 30, 2020).

⁴¹ *Staley v. Gilead Sciences, Inc.*, 446 F. Supp. 3d 578, 610, 612 (N.D. Cal. 2020).

⁴² *Sensipar*, 2020 WL 7022364.

⁴³ *Baltimore v. AbbVie*, 42 F.4th at 715.

⁴⁴ *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 261 (3d Cir. 2017).

⁴⁵ *Id.*

⁴⁶ *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829, 859 (N.D. Cal. 2021).

⁴⁷ *In re Lipitor*, 868 F.3d at 253–58.

⁴⁸ *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices & Antitrust Litig.*, 545 F. Supp. 3d 922, 994 (D. Kan. 2021).

⁴⁹ *Id.* at 1001.

⁵⁰ *Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 58–59 (1977).

In fact, as the Third Circuit explained, if the settling parties could “avoid liability for anticompetitive reverse payments simply by structuring them as two separate agreements,” *Actavis* would “become a penalty for bad corporate lawyering instead of anticompetitive conduct.”⁵¹

The Seventh Circuit’s failure to flexibly consider payment led it to treat the settlement here as one blessed by *Actavis*. But the non-concerning settlement that the *Actavis* Court analyzed took the form of a brand firm allowing the generic to enter early on the patent at the center of the litigation. The *Actavis* Court blessed those settlements because “a party with a claim . . . for damages receives a sum equal to or less than the value of its claim.”⁵²

This instruction was based on the critical distinction between settlements concerning the patent *at issue in the litigation* and those relating to patents *outside the litigation*. If the brand-name manufacturer conveys to the generic a type of consideration not available as a consequence of winning the patent litigation, the generic’s exclusion from the market cannot be directly traced to the strength of the brand’s patent.⁵³ On this point, the Seventh Circuit cited the example offered in *Actavis* of a generic facing liability of \$100 million with the brand forgiving \$60 million, effectively resulting in a payment from the generic to the brand of \$40 million.⁵⁴ This settlement falls within the range of potential expected litigation outcomes because if the brand wins, it would be entitled to \$100 million in damages, and if it loses, it would be entitled to zero. As a result, a \$60 million “payment” from the brand to the generic falls comfortably within the range of acceptable settlements.

By contrast, in *Baltimore v. AbbVie*, the settlement did not fall within the range of what

could be expected in patent litigation. In no scenario would a potential outcome of patent infringement litigation in the *United States* be early entry in *Europe*. This observation reveals the fallacy of the Seventh Circuit’s lament that “[i]f this is a cartel (AbbVie and its potential competitors carving up the market, 100% in AbbVie’s favor, from 2017 through 2022), then all settlements of patent cases violate the Sherman Act.”⁵⁵

Monopolization

On their second claim, the plaintiffs “allege[d] that AbbVie abused its monopoly over the U.S. market” when “it gummed up progress toward lower prices by obtaining and asserting ‘swaths of invalid, unenforceable, or noninfringed patents without regard to the patents’ merits.”⁵⁶ By “repeatedly and aggressively asserting this patent thicket during a lengthy, detailed regulatory process (and subsequent infringement litigation), AbbVie was able to delay its competitors [from entering] and avoid any real examination of the patents’ validity long enough to reap a few more years’ worth of monopoly profit on its lucrative, patent-protected product.”⁵⁷

The plaintiffs’ claims “depend[] on [the] premise that petitioning the government . . . can violate the antitrust laws if, in reality, that petitioning is nothing more than a sham meant to inhibit competition.”⁵⁸ In considering these sham claims, the Seventh Circuit made at least six errors, which implicated baseless petitioning, a “patent cap,” standing, the patent application and administrative review processes, and presumption of patent validity.

First, the Seventh Circuit did not address the lower court’s concession of at least “a kernel of objectively baseless petitioning.”⁵⁹ In particular,

⁵¹ *Fed. Trade Comm’n v. AbbVie Inc.*, 976 F.3d 327, 358 (3d Cir. 2020).

⁵² *Actavis*, 570 U.S. at 152.

⁵³ Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 9 (2014).

⁵⁴ *Id.* at 45.

⁵⁵ *Baltimore v. AbbVie*, 42 F.4th at 714.

⁵⁶ *In re Humira*, 465 F. Supp. 3d at 827.

⁵⁷ *Id.*

⁵⁸ *Id.* at 828.

⁵⁹ *Id.* at 832.

“AbbVie allegedly asserted without basis that if Amgen launched its biosimilar, it would infringe no less than sixty-six of AbbVie’s patents,” but “[w]hen Amgen disagreed, AbbVie failed to address Amgen’s concerns and declined to elaborate (even after Amgen repeatedly notified AbbVie of its failures to respond).”⁶⁰ According to the plaintiffs’ allegations, this was not unique. AbbVie “listed patents that were not infringed or that had been invalidated during its patent [exchange] with Boehringer,” and in its “prelitigation exchanges with Sandoz, AbbVie listed nine formulation patents that specified the use of a buffer system with ingredients that were *in neither Sandoz’s biosimilar nor Humira*—i.e., that were objectively baseless to assert.”⁶¹

Given all of this, the district court acknowledged that “it remains plausible that at least some of [AbbVie’s assertions] were objectively baseless.”⁶² The Seventh Circuit did not consider this relevant conduct, which was ironic given its recognition that the plaintiffs could present a legitimate claim “if AbbVie were to assert irrelevant patents against producers of biosimilar drugs.”⁶³ That is precisely what the plaintiffs alleged!

Second, the Seventh Circuit stated that the patent laws do not “set a cap on the number of patents any one person can hold”⁶⁴ and that the plaintiffs “have not offered to prove that all 132 patents are invalid or inapplicable to all potential biosimilar competitors.”⁶⁵ But these statements were incorrect on several levels.

As a factual matter, the plaintiffs did claim to “challenge all of AbbVie’s patent assertions” on the grounds of “obviousness, fraud, anticipation,

enablement and best mode, noninfringement, and unclean hands.”⁶⁶ As a practical matter, litigation typically does not implicate every potential patent. One study surveying litigation between biologics and biosimilars concluded that a subset of biologics was covered by roughly four times as many patents as were litigated.⁶⁷ And as a legal matter, AbbVie engaged in a pattern of litigation that involved settlements against nine biosimilars,⁶⁸ which the Supreme Court has explained may be associated with an increased likelihood that “judicial processes have been abused.”⁶⁹ In addition, the two elements at the core of a sham litigation claim—objectively baseless lawsuits and subjective interference with a rival through litigation⁷⁰—would seem to be satisfied in this case, at least at the pleading stage.

As discussed above, the district court acknowledged that some of AbbVie’s infringement claims were objectively baseless when the patented system did not appear in the biosimilar’s product. And subjective baselessness would seem to be plausibly alleged based on sophisticated attorneys claiming infringement of a system not at issue while senior AbbVie officials were “not very specific” about the portfolio, “ma[d]e it more difficult” for rivals to compete, explained how litigation “delay[s] biosimilars,” and had “confidence . . . built around a large portfolio of IP” as opposed to “any . . . single set of patents or individual patents.”⁷¹

The success of a sham litigation claim does not depend on whether plaintiffs can show that every patent is invalid. As the Ninth Circuit has explained, “even a broken clock is right twice a

⁶⁰ *Id.*
⁶¹ *Id.* (emphasis added).
⁶² *Id.*
⁶³ *Baltimore v. AbbVie*, 42 F.4th at 714.
⁶⁴ *Id.* at 712.
⁶⁵ *Id.* at 712–13.
⁶⁶ Reply Brief of Plaintiffs-Appellants, *UFCW Local 1500 Welfare Fund, et al. v. AbbVie Inc.*, 2021 WL 498873, at *26 (7th Cir. filed Feb. 1, 2021).
⁶⁷ Victor L. Van de Wiele et al., *Barriers to US Biosimilar Market Growth: Lessons From Biosimilar Patent Litigation*, 40 HEALTH AFFAIRS 1198, 1201 (2021) (presenting median figures of coverage by 90 patents and litigation involving 22).
⁶⁸ Consolidated Class Action Complaint and Jury Trial Demand, *Mayor & City Council of Baltimore v. AbbVie Inc.*, Case: 1:19-cv-01873, ¶ 211 (N.D. Ill. filed Aug. 9, 2019).
⁶⁹ *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972).
⁷⁰ *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993).
⁷¹ Complaint, *supra* note 68, ¶¶ 90, 96-97.

day.”⁷² Instead, it depends on elements like a pattern of potential sham litigation, together with objectively and subjectively baseless claims.⁷³

The Seventh Circuit’s third error was to assume that the plaintiffs in an antitrust case are not an appropriate party to challenge a patent. The court stated that “[t]he validity of the patents is a subject for dispute between AbbVie and the potential competitors, with review in the Federal Circuit.”⁷⁴ To similar effect: “[t]he would-be [biosimilar] entrants . . . were free to make arguments along these lines,” and “a separate antitrust suit by strangers to the patent litigation does not justify an effort to adjudicate by proxy what might have happened in the patent litigation, but didn’t.”⁷⁵ Further disclaiming any role for antitrust outside the setting of so-called *Walker Process* claims based on fraud on the Patent Office,⁷⁶ the court found it “hard to see how AbbVie can be penalized for its successful petitions to the Patent Office.”⁷⁷

This argument would have made sense before *Actavis*, at a time when courts assumed that there was no role for antitrust within the scope of the patent. *Actavis*, of course, overturned such deference, reaching back to 1926 to cite cases “both within the settlement context and without” in which it “struck down overly restrictive patent licensing agreements—

irrespective of whether those agreements produced supra-patent-permitted revenues.”⁷⁸ In addition, the Seventh Circuit’s argument does not recognize the unique context of reverse-payment settlements, which—as the FTC has explained—are “‘win-win’ for the companies” as “the brand and generic share the benefits of the brand’s monopoly profits” while “[c]onsumers lose.”⁷⁹ Putting all of the patent-challenge eggs in the basket of the party that is paid to drop its lawsuit does not make sense.⁸⁰

Fourth was the court’s consideration of the patent application process. The court concluded that “AbbVie’s patent applications cannot be called baseless” because “[a]fter all, the 132 patents issued.”⁸¹ This deference to the initial grant of the patent is not appropriate. The process of obtaining patents involves examiners having limited time to review each application, having incentives to grant patents, being hampered by the *ex parte* nature of the process, and often seeing initial determinations overturned in administrative proceedings or litigation.⁸²

The district court had rejected the plaintiffs’ allegations on the grounds that “numerous flaws in AbbVie’s patents and its assertion of them” did not demonstrate that the petitioning was objectively baseless” because “more than half

⁷² *USS-Posco Indus. v. Contra Costa County Building & Construction Trades Council, AFL-CIO*, 31 F.3d 800, 811 (9th Cir. 1994).

⁷³ In the settlement context, the Supreme Court explained that the “relevant anticompetitive harm” is the “prevent[ion of] the risk of competition,” and this applies where there is “even a small risk of invalidity” (in other words, where the patent is most likely valid). 570 U.S. at 157.

⁷⁴ *Baltimore v. AbbVie*, 42 F.4th at 713.

⁷⁵ *Id.* at 714.

⁷⁶ *Walker Process Equipment, Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172 (1965). In *Baltimore v. AbbVie*, the Seventh Circuit asserted that the plaintiffs “have abjured any reliance on the *Walker Process* doctrine,” 42 F.4th at 713, but that is not consistent with the complaint. See Complaint, *supra* note 68, ¶¶ 114–120.

⁷⁷ *Baltimore v. AbbVie*, 42 F.4th at 713.

⁷⁸ 570 U.S. at 150.

⁷⁹ FED TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 1 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

⁸⁰ Michael A. Carrier, *Pay-for-Delay: Who Does the Generic Industry Lobby Represent?*, CPI ANTITRUST CHRONICLE (May 2020).

⁸¹ *Baltimore v. AbbVie*, 42 F.4th at 713. The court also was not correct in assuming that “[w]eak patents are valid,” *id.*, as the plaintiffs challenged many of these patents as invalid on the grounds that they did not satisfy novelty, nonobviousness, enablement, or best mode requirements, and as unenforceable on the basis of inequitable conduct. See Complaint, *supra* note 68, ¶¶ 108–140.

⁸² See, e.g., Michael A. Carrier, Response to Senator Grassley’s Questions for the Record, Sen. Jud. Comm. Hearing on “IP and the Price of Prescription Drugs: Balancing Innovation and Competition,” at 3–4, May 28, 2019, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3442654; Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data* (Nat’l Bureau of Econ. Rsch., Working Paper No. 20337, 2014), <https://www.nber.org/papers/w20337.pdf>; Michael D. Frakes & Melissa F. Wasserman, *Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO’s Granting Patterns*, 66 VAND. L. REV. 67 (2013).

(53.4%) of AbbVie’s patent applications resulted in patents.”⁸³ According to the court, “a batting average of .534 [is] too high to plausibly allege sham petitioning as a matter of law.”⁸⁴ The Seventh Circuit favorably cited this figure, calling it “stellar in patent practice and unheard-of in baseball.”⁸⁵ But AbbVie’s patent application success rate is an inappropriate source of comfort; indeed, no prior court has relied on it in this context. The more appropriate measure would be AbbVie’s rate of success when patent validity is litigated.⁸⁶

Fifth, the district court found that “AbbVie’s success rate during [the Patent Office proceeding known as] *inter partes* review [IPR] was even higher, and establishes that AbbVie’s conduct there was not objectively baseless, either.”⁸⁷ The court stated that “[a]lthough the Patent Trial and Appeal Board [PTAB] found invalid three of the five AbbVie patents that it reviewed (and even though AbbVie terminated the other two before a final determination could be reached), . . . the PTAB declined to initiate *inter partes* review with regard to thirteen of AbbVie’s other patents.”⁸⁸ The Seventh Circuit stated that “13 . . . of AbbVie’s patents were solid enough not to need review.”⁸⁹

Declining to initiate IPR, however, has limited relevance in a *court’s* determination of patent validity. A petitioner seeking to use IPR can raise challenges based on only anticipation or nonobviousness (not patentable subject matter, utility, enablement, or written description), and can introduce prior art solely in the form of

patents or printed publications.⁹⁰ By contrast, courts have authority to consider a broader variety of issues and evidence in determining a patent’s validity.

Sixth, the Seventh Circuit relied on a “presumption of patent validity” to explain why the plaintiffs could not challenge patents.⁹¹ But for several reasons, this is not persuasive.⁹² For starters, the presumption is only a “procedural device” for allocating burdens of production and persuasion at trial, not “evidence which can be ‘weighed’ in determining likelihood of success.”⁹³ In addition, regardless of a presumption on validity, it is, as the Supreme Court has acknowledged, “well established that the burden of proving infringement generally rests upon the patentee.”⁹⁴

The Supreme Court also has recognized the importance of testing weak patents and ensuring that the public does not suffer the adverse effects of invalid ones.⁹⁵ That matters because empirical studies have consistently shown that a significant percentage of granted patents are invalid. One study, for example, concluded that the vast majority—89%—of patents in settled litigation are secondary patents covering ancillary aspects of drug innovation (such as formulation or composition) rather than the active ingredient, with the brand firm far less likely to win on these secondary

⁸³ *In re Humira*, 465 F. Supp. 3d at 830.

⁸⁴ *Id.* It speaks volumes that each of the cases the district court cited in support of its “batting average” was based on success in litigation, not patent acquisition. See *id.*

⁸⁵ *Baltimore v. AbbVie*, 42 F.4th at 713.

⁸⁶ *In re Humira*, 465 F. Supp. 3d at 830–31.

⁸⁷ *Id.* at 831.

⁸⁸ *Id.*

⁸⁹ *Baltimore v. AbbVie*, 42 F.4th at 713.

⁹⁰ 35 U.S.C. § 311(b).

⁹¹ *Baltimore v. AbbVie*, 42 F.4th at 713.

⁹² See generally Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 62–65 (2009) (explaining why the presumption of patent validity is not dispositive in this context).

⁹³ *New Eng. Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992).

⁹⁴ *Medtronic, Inc. v. Mirowski Fam. Ventures, LLC*, 571 U.S. 191, 198 (2014). See also *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008) (“the patentee bears the ultimate burden of proof to demonstrate infringement”); *In re Glumetza Antitrust Litig.*, 2021 WL 1817092, at *9 (N.D. Cal. May 6, 2021) (“[t]he patent owner *always* bears th[e] burden” of showing noninfringement) (emphasis in original).

⁹⁵ *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 264 (1979); *United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973); *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).

patents (32%) than on active ingredient patents (92%).⁹⁶

Conclusion

In conclusion, the issues presented by multiple settlements and sham litigation in the context of

patent thickets are challenging and nuanced. But the Seventh Circuit's unsupported analyses of these issues did not do any favors to future courts or to consumers suffering from potentially anticompetitive conduct on the best-selling drug in the United States.

⁹⁶ C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 *SCIENCE* 1386, 1387 (2013). For a discussion of other studies, see Carrier, *supra* note 92, at 64–65.