UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: HUMIRA (ADALIMUMAB) ANTITRUST LITIGATION	Case No. 1:19-cv-1873 Hon. Manish S. Shah Magistrate Judge Jeffrey Cummings JURY TRIAL DEMANDED

REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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Plaintiffs' opposition deploys a strategy of disclaim–withdraw–divert. Plaintiffs first contend that AbbVie created an unlawful monopoly by obtaining "too many" patents. Plaintiffs assert that their theory does not rest solely on the same "accumulation" theory that the Supreme Court has rejected; yet their brief asserts exactly that theory, complete with a section entitled "Large accumulations of patents are likely to create significant anticompetitive effects." Opp. 18. Plaintiffs also claim they are not asserting *Walker Process* fraud, *id*. at 11 n.4, or a sham litigation challenge, *id*. at 22, only to later argue watered-down versions of these claims. While Plaintiffs spend a large portion of their brief discussing what they are not alleging, they do not identify any unlawful conduct. And in all events, *Noerr–Pennington* immunizes AbbVie's alleged conduct.

Plaintiffs have been forced to completely withdraw their second theory of liability—that AbbVie allegedly granted Amgen five months' exclusivity. Opp. 30 n.15. They continue to press their third theory, that AbbVie and the biosimilar Defendants entered into unlawful early-entry settlement agreements, but this theory fares no better. Plaintiffs divert focus to the various forms of reverse payments in other cases, but ignore that there is no reverse payment here ***at all***. The agreements simply permit early entry—"***the very type of settlement sanctioned by the [Supreme] Court***," *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *14 (S.D.N.Y. Sept. 22, 2015) (emphasis added)—and require the biosimilar Defendants to pay royalties to AbbVie. Plaintiffs then attempt to mischaracterize these patent licenses as unlawful market allocations, ignoring that Congress expressly permits selective geographic licensing of patents "to the whole or ***any specific part*** of the United States." 35 U.S.C. § 261 (emphasis added). Courts uniformly—and correctly—extend this principle to global patent portfolios, allowing patent holders to license their patents on a jurisdiction-by-jurisdiction basis without facing antitrust liability.

Plaintiffs also have no good answer to the lack of antitrust injury. They admit that they are not challenging the validity of ***all*** AbbVie patents, Opp. 49, and there can be no injury when even

one patent "would have prohibited [ ] entry into the market place." *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1369 (S.D. Fla. 2004). Plaintiffs also fail to identify any facts suggesting that a biosimilar would have entered the U.S. market sooner but for AbbVie's patents and the settlements they challenge. Instead, Plaintiffs offer speculation that biosimilars could have prevailed in litigation with AbbVie or entered into hypothetical settlements with earlier entry dates. But Plaintiffs' allegations undermine each theory, and neither theory is plausible.

Finally, Plaintiffs' state-law consumer fraud and antitrust claims fail alongside their federal claims, and on additional state-specific grounds. The Complaint should be dismissed.

I. PLAINTIFFS' "PATENT THICKET" CLAIMS FAIL AS A MATTER OF LAW

In twenty pages of briefing on their "thicket" theory, Plaintiffs fail to identify any unlawful conduct. They disclaim reliance on the already-rejected "accumulation of patents" theory, Opp. 10 n.3; concede that they are not asserting a *Walker Process* fraud claim, *id*. at 11 n.4; and contend that they are not asserting a *PRE* sham litigation claim, *id*. at 22—each of which is precluded as a matter of law. Plaintiffs' Section 2 claim against AbbVie fails.

A. Plaintiffs Have Not Pleaded Unlawful Conduct Based On AbbVie's "Thicket"

The Complaint pleads that "the sheer volume of patents and claims" is what "keep[s] biosimilars off the market." Compl. ¶ 85. Yet Plaintiffs now tell the Court that they "do not assert an 'accumulation of patents' claim." Opp. 10 n.3. This retreat is hardly surprising; the Supreme Court held 70 years ago that the "mere accumulation of patents, no matter how many, is not in and of itself illegal" under antitrust laws, regardless of allegations that owning many patents threatens competition "by means of the overpowering threat of disastrous litigation." *Automatic Radio Mfg. v. Hazeltine Research*, 339 U.S. 827, 834 (1950). Still, Plaintiffs insist that "[l]arge accumulations of patents are subject to special scrutiny" and that there are "dangers inherent in vast accumulations of patents." Opp. 18. But those arguments are foreclosed by *Automatic Radio*'s clear language—

"***no matter how many***"—which Plaintiffs never address. Nor do they explain at what threshold an accumulation of patents becomes sufficiently "large" or "vast" to receive "special scrutiny" or be "danger[ous]," *id*., ducking the question *how many patents are too many? See* Defs. Br. 13.

Plaintiffs cite two cases to support their "large/vast accumulation" theory, *see* Opp. 19-21, but neither overcomes *Automatic Radio* (nor could they). *Kobe, Inc. v. Dempsey Pump Co.*, 198 F.2d 416 (10th Cir. 1952)—often criticized[1]—concerns "patent pooling," in which competitors "contribute[ ] one or more of [their] patents ... to form a collection of patents." *Matsushita Elec. Indus. Co. v. Cinram Int'l, Inc.*, 299 F. Supp. 2d 370, 373 (D. Del. 2004). Pools are subject to scrutiny because they can "facilitate collusion among competitors." *Princo Corp. v. ITC*, 616 F.3d 1318, 1335 (Fed. Cir. 2010) (en banc). There is no allegation of that here. Just the opposite, Plaintiffs allege that AbbVie shut biosimilars out of the market, not joined forces with them.

Intellectual Ventures I LLC v. Capital One Financial Corp. ("*IV*"), 99 F. Supp. 3d 610 (D. Md. 2015), is equally distinguishable. The defendant there was a non-practicing entity that engaged in "strategic *ex post* patent aggregation," which is "the opposite" of "the patent aggregation that *bona fide* operating companies practice" to protect "their own productive commercial operations." *Id.* at 626. It therefore is unremarkable that the *IV* court was "[u]npersuaded" by *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195 (2d Cir. 1981), Opp. 20, given that the defendant in *SCM* "acquired a number of patents related to its own products," *IV*, 99 F. Supp. 3d at 626, i.e., it produced goods and was a practicing entity—like AbbVie. The allegations here and the facts of *SCM* thus are analogous to one another, whereas *IV* is "distinguished readily." *Id.*

As antitrust scholars (cited by Plaintiffs, Opp. 31 n.16) make clear, "we would never hold internal patent development to be a § 2 exclusionary practice because we do not wish to discourage

[1] Courts criticize *Kobe* as "inconsistent with a modern understanding of intellectual property and competition law." *Hynix Semicond. Inc. v. Rambus Inc.*, 527 F. Supp. 2d 1084, 1096 (N.D. Cal. 2007).

innovation, even by monopolists." Ex. 1, Areeda & Hovenkamp, *Antitrust Law*, ¶ 704c. AbbVie, of course, is a "*bona fide* operating compan[y]" with "patents related to its own product[ ]." *IV*, 99 F. Supp. 3d at 626. Plaintiffs cite no case endorsing an accumulation theory under this scenario.

This is not a failure Plaintiffs can cure. In claiming that AbbVie's reliance on *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411 (Fed. Cir. 1987), is "misplaced," Plaintiffs note that "in that case, 'there [wa]s no indication in the briefs or the record that the interest sought to be protected by the antitrust laws, *i.e.*, the welfare of the consumer, was adversely affected by anything Manitowoc did.'" Opp. 24. The footnote to Plaintiffs' quotation explains ***why*** the interest sought to be protected was not adversely affected: Because "[m]ere procurement of a patent ... cannot in itself violate the antitrust laws." 835 F.2d at 1418 n.16. Thus, for Plaintiffs to say that AbbVie's procurement of patents "has delayed and will delay lower-priced biosimilars for years," Opp. 24, would require holding AbbVie liable for others' business decisions not to enter the market and risk infringement ***based solely on AbbVie owning patents*** ("[m]ere procurement"). That's not the law.

Nor is Plaintiffs' theory novel such that it should be tested under the Rule of Reason or allowed factual development. AbbVie cited a decision in which a patent holder was accused of a Section 2 violation for "***accrual of a patent 'thicket,'***" but the district court held that the defendant was immune under *Noerr–Pennington*. *Proctor & Gamble Co. v. Paragon Trade Brands, Inc.* (*P&G*), 61 F. Supp. 2d 102, 110 (D. Del. 1996). Plaintiffs never challenge that *P&G* addressed the kind of thicket claim they now assert, but instead only incorrectly claim that *P&G* applied the wrong immunity standard. Opp. 22; *see infra* pp. 5-8. Thus, while it might be true that "[n]o court has ruled on the legality of a patent thicket" for biologic drugs, Opp. 19, it does not follow that "courts have not addressed" Plaintiffs' ***legal theory***, *id.* at 12. They have, and they rejected it.

B. Alleged Patent Invalidity Cannot Give Rise To Antitrust Liability

Plaintiffs next concede (as they must, because they lack standing) that they are "not

assert[ing] a *Walker Process* claim." Opp. 11 n.4. Rather than asserting fraud, Plaintiffs challenge the ***validity*** of AbbVie's patents, even though many core patents have withstood validity challenges in IPR. *E.g.*, *id.* at 17 (describing as "anticompetitive conduct" AbbVie asserting patents against biosimilar manufacturers "despite knowing that many of [the patents] were invalid, unenforceable, or not infringed"); *see* Defs. Br. 6-7. That focus suffers from two flaws.

First, just as Plaintiffs lack standing as indirect purchasers to contest patents as fraudulently procured, Defs. Br. 15, they also lack standing to challenge them on other grounds. It is well-settled that even direct purchasers are "unable to challenge a patent's validity," *Kroger v. Sanofi-Aventis*, 701 F. Supp. 2d 938, 963 (S.D. Ohio 2010), and indirect purchasers—who are another level removed—fare no better. *In re Ciprofloxacin Antitrust Litig.*, 363 F. Supp. 2d 514, 542 (E.D.N.Y. 2005) (leaving it Congress to give indirect purchasers standing to contest validity).

Second, even assuming, *arguendo*, that certain AbbVie patents were later invalidated, that still could not subject AbbVie to liability. Defs. Br. 14, 19. Plaintiffs address ***none*** of AbbVie's cases on this point, but question the application review process, arguing that AbbVie "cannot demonstrate as a matter of law the robustness of the review of *AbbVie's* patent applications." Opp. 17 n.6. But patents are presumed valid, 35 U.S.C. § 282(a), and even if "the patent system might be thought to be ... in need of reform," "the antitrust laws were not designed to repair other government regulatory processes." Ex. 1, Areeda & Hovenkamp, ¶ 704b4. Thus, while Plaintiffs urge the Court to "wait for summary judgment," Opp. 22, there is no need to indulge Plaintiffs' invalidity attacks—now or ever—because "invalidity has no probative value ... in attempting to establish any antitrust violation," *Bendix Corp. v. Balax, Inc.*, 471 F.2d 149, 154 (7th Cir. 1972).

C. *Noerr–Pennington* Immunizes The Acquisition And Enforcement Of Patents

Plaintiffs' brief also confirms that *Noerr–Pennington* bars their "thicket" claims. Plaintiffs do not attempt to address the "objectively baseless" standard for sham petitioning under *PRE, Inc.*

v. Columbia Pictures Industries, Inc., 508 U.S. 49 (1993)—which requires Plaintiffs to plead that AbbVie could not have had even a "***reasonabl[e]*** belie[f] that there is a ***chance*** that [a] claim ***may*** be held valid upon adjudication," *id.* at 62-63 (emphases added). Defs. Br. 17-20. Nor do Plaintiffs meaningfully address *P&G*, which found immunity under *PRE* with nearly identical allegations regarding "***accrual of a patent 'thicket.'***" 61 F. Supp. 2d at 110 (emphasis added); Defs. Br. 17.

Plaintiffs argue that "objectively baseless" is not the proper standard because AbbVie's patent applications and lawsuits are a "series" of petitions, subject to *California Motor Transport v. Trucking Unlimited*, 404 U.S. 508 (1972), whereas *PRE* "applies to one petition." *See* Opp. 26. This fails. Although other courts recognize that different standards apply for serial petitioning versus a single petition, "the Seventh Circuit has not recognized a different standard." *U.S. Futures Exchange, LLC v. Bd. of Trade of Chi., Inc.*, 346 F. Supp. 3d 1230, 1252 (N.D. Ill. 2018).

Nor can Plaintiffs state a claim under the inapplicable *California Motor* standard in any event. Plaintiffs do not allege facts showing that AbbVie petitioned the government "without probable cause, and regardless of the merits." *Calif. Motor*, 404 U.S. at 512. As Plaintiffs' case recognizes, "[t]he fact that more than half of all [government petitions] ... turn out to have merit cannot be reconciled with the charge that [a party is petitioning] willy-nilly without regard to success." *USS-POSCO Indus. v. Contra Costa Trades Council*, 31 F.3d 800, 811 (9th Cir. 1994).

For patent applications,[2] by Plaintiffs' own accounting, AbbVie has "a batting average exceeding .500." *See id.*; Compl. ¶ 99 (247 applications, 132 patents). Plaintiffs characterize this as "barely half," Opp. 27, but AbbVie's alleged success rate (53%) is ***higher*** than in *USS-POSCO* (51%), a level which the court said "foreclose[d] any possibility" of overcoming *Noerr-*

[2] The Court should not consider AbbVie's petitioning the Patent Office for issuance as anticompetitive at all, because patent ***applications*** confer no exclusionary right. *See Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979). Thus, as a matter of law, AbbVie's pending applications could not keep biosimilars off the market or otherwise interfere with their businesses.

Pennington. 31 F.3d at 811. Plaintiffs try to dismiss AbbVie's successes as "irrelevant," Opp. 27, but they ***are*** relevant, as Plaintiffs' own cases show. *USS-POSCO*, 31 F.3d at 811; *see Waugh Chapel S., LLC v. United Food & Commercial Workers Union*, 728 F.3d 354, 365 (4th Cir. 2013) (Opp. 26) ("a one-out-of-fourteen batting average at least suggests" sham litigation).

Plaintiffs' argument about AbbVie's assertion of its patents fares no better. First, AbbVie sued only three biosimilar companies (Compl. ¶¶ 148, 166, 181), and never sued the same one twice. That is far afield of *USS-POSCO* (29 suits against one party) and *Waugh Chapel* (14 suits against one party). *Compare ERBE Elektromedezin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1292 (Fed. Cir. 2010) (three lawsuits do not implicate *California Motors* standard). That multiple companies sought FDA approval to sell a biosimilar, moreover, cannot be held against ***AbbVie***; otherwise, patents would be good as to only the first infringers, and later market entrants could raise antitrust claims simply by waiting. That argument fails. *Kaiser Found. Health Plan, Inc. v. Abbott Labs.*, 552 F.3d 1033, 1047 (9th Cir. 2009) ("It is true that Abbott was litigious, but .... [t]he volume of Abbott's suits was dependent on the number of generic companies attempting to enter the terazosin hydrochloride marketplace, a matter over which Abbott had no control.").

Second, no AbbVie lawsuit was unsuccessful on the merits. The *Kaiser* plaintiffs argued that the *California Motor* standard should apply where the patentee won 7 of 17 suits (41%) and "lost the other ten." 552 F.3d at 1046. The court did not even bother to determine the proper standard for immunity, because "even under" *California Motor*, the antitrust claims failed. *Id.* Here, Plaintiffs do not allege that AbbVie has lost ***any*** lawsuits. All three cases settled, with the biosimilars paying a royalty to AbbVie, confirming that the suits were not filed "willy-nilly." *USS-POSCO*, 93 F.3d at 811; *see Theme Promotions, Inc. v. News Am. Mktg. FSI*, 546 F.3d 991, 1008 (9th Cir. 2008) ("[t]he fact that this ongoing litigation settled suggests that the original suit was not objectively baseless"); *Rubloff Dev. Grp, Inc. v. Supervalu, Inc.*, 2013 WL 441152, at *3 (N.D.

Ill. Feb. 5, 2013) ("Because [plaintiff] settled the three lawsuits at issue for a substantial sum, the lawsuits cannot be objectively meritless."). Plaintiffs also do not dispute that AbbVie prevailed in 13 of 20 (65%) IPRs, Defs. Br. 6-7—a higher success rate than in *USS-POSCO* (51%).

Plaintiffs' "entire course of conduct" argument, *see* Opp. 27, also runs headlong into *Pennington* itself, which held that petitioning, "either standing alone ***or as part of a broader scheme***," and "even though intended to eliminate competition," does not violate the antitrust laws. *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965) (emphasis added). Courts thus have resoundingly rejected *Kobe* (Opp. 19-20) in light of later decisions. *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 429 (D. Del. 2006) ("*Kobe* ... is contrary to more recent pronouncements by the Supreme Court concerning *Noerr* immunity."); *see Hynix*, 527 F. Supp. 2d at 1096 (*Kobe*'s "understanding of antitrust law ... does not square with modern antitrust law").[3]

II. PLAINTIFFS' SECTION 1 CLAIMS FAIL AS A MATTER OF LAW

Plaintiffs have withdrawn their theory regarding alleged Amgen exclusivity, Opp. 30 n.15; claims based on that theory should be dismissed. Their other theories based on the settlements also fail. Plaintiffs cannot articulate a reverse payment subject to antitrust scrutiny. Nor can they circumvent *Actavis* by asserting a market division theory. The settlements are not unlawful.

A. Plaintiffs' Unprecedented Multi-Jurisdiction Settlement Theory Fails

Plaintiffs cannot escape the Supreme Court's instruction that litigants may, without risking any antitrust scrutiny, settle patent litigation by compromising on the defendant's market-entry date (so long as that date is prior to patent expiration). *FTC v. Actavis*, 570 U.S. 136, 158 (2013). Plaintiffs do not dispute that the settlements here fit that exact description. *See* Defs. Br. 23-24.

[3] In Plaintiffs' lone cited case, *In re Neurontin Antitrust Litig.*, 2009 WL 2751029 (D.N.J. Aug. 28, 2009), the "overall monopolization scheme" involved illegal conduct; even if the individual acts were not antitrust violations, they still violated other laws. *Id.* at *5 (scheme to "submit false and fraudulent information to the FDA"). AbbVie's patent assertion, by contrast, is a lawful exercise of patent rights.

Nor do they address the myriad cases holding that early-entry-only settlements are not subject to antitrust review: "[T]he *Actavis* Court expressly identified early-entry licensing as a traditional form of settlement ***whose legality the opinion took pains not to disturb***." *King Drug Co. v. SmithKline Beecham Corp.*, 791 F.3d 388, 407 (3d Cir. 2017) (emphasis added); Defs. Br. 21-22.

Plaintiffs instead insist that there is a payment in the form of the biosimilars' "immediate, date-certain entry in Europe." Opp. 37. But ***any*** early-entry settlement creates "market certainty that [ ] licenses confer[ ]." *Id*. at 42. And while Plaintiffs claim that European entry is worth "hundreds of millions of dollars, *id.* at 37, Judge Posner warned in *Asahi Glass* that "*any* settlement agreement can be characterized as involving 'compensation' to the defendant." *Asahi Glass Co. v. Pentech Pharms. Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003). Where that "compensation" is derived entirely from the opportunity to compete, it is not a reverse payment. *Id.*

Plaintiffs purport to address *Asahi Glass* in two ways, but neither casts doubt on its reasoning or outcome. First, Plaintiffs suggest it is "outdated" and call its analysis "dicta." Opp. 44. But to conclude that the settlement there—which provided for different early-entry dates in different jurisdictions—did not include a reverse payment, Judge Posner contrasted those terms with settlements that do involve reverse payments. *See* 289 F. Supp. 2d at 994. Plaintiffs do not undermine the logic of his legal analysis. The "outdated" claim also is wrong. Courts continue to rely on *Asahi Glass* to reject claims like Plaintiffs' post-*Actavis*. Defs. Br. 25 n.11 (citing *Actos*).[4]

Second, in a footnote, Plaintiffs claim that, unlike in *Asahi Glass*, the agreements here "avoided competition in the United States entirely." Opp. 44 n.21. But that simply is not the

[4] The *Actos* court cited *Asahi Glass* to hold that "a reading of *Actavis* that would compel antitrust scrutiny of a settlement regardless of whether its terms could reasonably be construed as a large and unjustified reverse payment would ... subject virtually *any* settlement to antitrust scrutiny—a result the [*Actavis*] Court could not have intended." 2015 WL 5610752, at *14. Plaintiffs have no answer for *Actos* either (which also addressed early-entry-only agreements) beyond their unsupported claims that it is "flawed" and based on "an overly narrow interpretation" of *Actavis*. Opp. 44.

case—the agreements provide for early entry in 2023. Compl. ¶ 211. Under Plaintiffs' logic, an early-entry-only settlement—even one where entry happens a week later—still would be unlawful because ***immediately*** after the settlement, the competitive landscape is unchanged. In other words, unless a settlement allowed ***immediate*** entry, while the ink was still drying, it would be "avoiding competition entirely." Opp. 44 n. 21. To adopt such a holding would require overruling *Actavis*.

Rather than address Defendants' analogous cases, Plaintiffs cite post-*Actavis* cases involving ***actual*** reverse payments, most notably no-authorized-generic ("no-AG") agreements, in which the "brand manufacturer [promises] not to market an AG version of the brand drug for some period of time after the first generic enters." *In re Zetia Antitrust Litig.*, 2019 WL 1397228, at *6 (E.D. Va. Feb. 6, 2019).[5] No-AG agreements are nothing like early-entry licenses. In no-AG cases, the patent holder relinquishes value by agreeing not to compete with the licensee: Patentees "compensate a [generic's] delayed entry by ensuring that it will face no generic competition during its 180-day exclusivity period." *Id.* at *6. It is this ***agreement not to compete*** that courts conclude may amount to an unlawful transfer of value. *See Opana*, 162 F. Supp. at 717 ("[C]ommitment not to produce an AG means that it gave up the valuable right to capture profits in the new two-tiered market."). Plaintiffs do not allege that AbbVie gave up anything like that here.

Plaintiffs, tellingly, never identify a single court that has found a reverse payment when a party grants patent licenses to allow entry in different geographic markets at different times. Defs. Br. 22. For good reason: If accepted, Plaintiffs' theory would imperil global patent settlements. While Plaintiffs claim that they "do not seek to forbid" such settlements, Opp. 43, they fail to

[5] *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 717 (N.D. Ill. 2016) ($33-$49 million under no-AG agreement plus $10 million cash); *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017) (release from damages claim secured by $200 million injunction bond for a $1 million payment); *King Drug*, 791 F.3d at 393 (no-AG agreement); *In re Nexium Antitrust Litig.*, 968 F. Supp. 2d 367 (D. Mass. 2013) (same); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307 (D.R.I. 2017) (no-AG agreement plus exclusivity); *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA*, 74 F. Supp. 3d 1052 (N.D. Cal. 2014) (no-AG agreement plus $96 million in product).

explain how a company could ever settle a multi-jurisdiction patent dispute without liability unless it had the same patent estate everywhere and provided the same entry date in each country, Defs. Br. 27. And subjecting early-entry agreements to antitrust scrutiny puts courts in the untenable position of having to judge whether entry is "too early," and risks chilling competition-enhancing agreements the antitrust laws seek to encourage. *Cf. Brooke Grp. v. Brown & Williamson Tobacco*, 509 U.S. 209, 226 (1993) (rejecting antitrust challenge based on lack of administrable standard to identify anticompetitive discounts and risk of "chill[ing] the very conduct" antitrust laws protect).

Plaintiffs also devote much of their opposition to arguments that Defendants do not make. Plaintiffs assert that a reverse payment need not be "stacks of cash." Opp. 41. But Defendants never argue otherwise. The point is that there is no reverse payment because AbbVie never agreed to "pay the alleged infringer"—at all, in any form. *Actavis*, 570 U.S. at 141. Plaintiffs also argue that Defendants seek to "consider the parts" of the settlements in "isolation." Opp. 38. But Defendants are simply adhering to the rule from *Loestrin*. Rather than always requiring "a broad and holistic look at the deal," Opp. 39, the court explained that for "global, complex settlement agreements," courts should first assess whether "each component" is a reverse payment, and ***only if*** a component is a reverse payment is it "appropriately part of the calculus" to "factor into the second step of the analysis," i.e., the "holistic" view for which Plaintiffs advocate. 261 F. Supp. 3d at 331. Here, no component is a reverse payment, and thus the inquiry ends after step one.[6]

Finally, the settlement terms from which Plaintiffs seek to infer an unlawful *quid pro quo* are consistent with lawful conduct. Plaintiffs allege major differences in the strength of AbbVie's

[6] This is consistent with the FTC's approach. *See* Defs. Br. 23 n.10. Plaintiffs seek to distinguish *FTC v. Cephalon* in that it addresses only situations in which there are two separate settlements agreements, Opp. 44 n.22, but Plaintiffs do not explain why that distinction matters. In any event, the relevant provision of the settlement in that case addresses agreements entered within 30 days of the agreement in question such that they should be considered together. The FTC nevertheless blesses the agreements, whether considered together or separately, so long as they contain nothing more than early entry—just like the agreements here.

patents and litigation positions in the United States relative to Europe, Compl. ¶¶ 90, 202, Opp. 41, and do not contest that other biosimilars, which did not receive a European license, negotiated similar U.S. entry dates to the ones that did, Defs. Br. 26. Plaintiffs thus allege perfectly rational—and legal—explanations for the very conduct they attack. A complaint "must be dismissed" where, as here, it merely pleads allegations that are "not only compatible with, but indeed [are] more likely explained by, lawful conduct." *Ashcroft v. Iqbal*, 556 U.S. 662, 680 (2009).

B. The Early-Entry Patent Settlements Are Not Market Division Agreements

Recognizing that their reverse-payment claims fail as a matter of law, Plaintiffs attempt to plead around *Actavis* by branding the settlements as "market division agreements" subject to *per se* or "quick look" treatment. Opp. 30-36. But courts universally reject such attempted end-runs, holding that the Rule of Reason applies to patent settlements. Defs. Br. 27-29. Plaintiffs cite no case to the contrary. And even under their alternative theory, Plaintiffs' claims still fail.

Plaintiffs do not dispute that AbbVie continues to compete in the United States and Europe, confirming that AbbVie and the biosimilar Defendants did not agree to "never compete[ ] in the same market." *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49 (1990). Lacking the *sine qua non* of market division, Plaintiffs retort that AbbVie "was permitted to keep for itself the entire U.S. market." Opp. 32. But what AbbVie was "permitted" to do simply reflects AbbVie's patent rights.

Congress granted to patent holders the right to "grant and convey an exclusive [patent] right ... to the whole ***or any specified part*** of the United States." 35 U.S.C. § 261 (emphasis added). As one court explained, "***as a matter of law***, a patent licensor's use of geographic restrictions ... to divide territories into ones of primary or exclusive jurisdiction constitutes a lawful application of the rights derived from a patent grant." *Miller Insituform, Inc. v. Insituform of N. Am., Inc.*, 605 F. Supp. 1125, 1130-31 (M.D. Tenn. 1985) (emphasis added) (dismissing § 1 claim). Thus, for example, it is a "valid exercise of [ ] patent rights" for a patentee to license "that portion of the

United States lying east of the Mississippi River" but to "reserve[ ]" the "western territory" for itself. *United States v. Crown Zellerbach Corp.*, 141 F. Supp. 118, 127 (N.D. Ill. 1956).

The same analysis applies when foreign patent rights are involved. *Dunlop Co. v. Kelsey-Haynes Co.*, 484 F.2d 407 (6th Cir. 1973), is directly on point. There, the plaintiff claimed that the defendant's foreign licenses, which allowed competitors to sell patented products abroad but not in the United States, "constitute[d] an illegal division of world markets." *Id.* at 417. The court disagreed: "If one who received a patent from the United States may so restrict his licenses without violating the domestic antitrust laws, ***it would seem clear that a patentee could do the same thing with foreign licenses without violating the antitrust laws of this country***." *Id.* (emphasis added); *see also United States v. Westinghouse Electric Corp.*, 648 F.2d 642, 648 (9th Cir. 1981) ("To find an antitrust violation because [a patentee], having licensed its foreign patents ... but ha[ving] not granted ... licenses of its United States patents, ... would severely limit the protection extended by Congress in the laws under which [the patentee's] United States patents were granted.").

Plaintiffs assert that "[t]erritorial divisions are not immunized from *per se* treatment simply because ***intellectual property*** rights are involved." Opp. 31 (emphasis added). But they ignore that Congress put patents in a class of their own within "intellectual property." *See* 35 U.S.C. § 261. Not surprisingly, Plaintiffs' lead case for this claim involved trademarks, not patents. *See United States v. Sealy*, 388 U.S. 350, 355 (1967). And it was "flagrant and pervasive price-fixing"—not any territorial aspect—that was the basis for the Court holding the agreement to be unlawful. *See id.* at 355-56; *see Timken Roller Bearing Co. v. United States*, 341 U.S. 593, 595-96, 598-99 (1951) (Opp. 31) (agreement for trademarked goods involved "fix[ing] prices on products").

Only one of Plaintiffs' cases involves patents, but *Tawfilis v. Allergan, Inc.*, is readily distinguishable. The agreement there restricted where the patentee (not the licensee) could sell the patented product. 157 F. Supp. 3d 853, 858 (C.D. Cal. 2015). By contrast, the agreements here

do not restrict AbbVie, geographically or otherwise. That distinction is critical, because "[w]hile the patentee remains free to protect himself, within the scope of the patent, by restricting the ***licensee***, restrictions imposed upon the ***patentee*** by the licensing agreement must be viewed in a different light." *Crown Zellerbach*, 141 F. Supp. at 127 (emphases added). Plaintiffs allege the former (restrictions on licensees), whereas *Allergan* involved the latter (restrictions on patentee).

Plaintiffs' reliance on Areeda & Hovenkamp, Opp. 31 n.6, also is misplaced. The *A* and *B* widget hypothetical concerned "an agreement between a patent holder and another firm that is ***not a licensee***, but simply promises not to engage in competition with the patentee." Ex. 1, Areeda & Hovenkamp, ¶ 2044a1 (emphasis added). Here, of course, the biosimilars are licensees. Plaintiffs misleadingly swap out key language on this point with an ellipsis—with the emphasized text omitted from Plaintiffs' brief: "A leading treatise notes that 'if A owned a patent on a particular type of widget and entered into an agreement with B that in exchange for a monetary payment B would simply not produce that type of widget in California, that agreement ***would not be the transfer of any rights under the patent***.'" Opp. 31 n.16.

Plaintiffs' theory is further flawed because it asserts only a ***temporal*** limit on market entry, not a geographic one. The only restriction on the biosimilars' ability to compete depends on ***when*** they can enter the market. Plaintiffs cite *Blackburn v. Sweeney*, Opp. 31, but not only did that case not involve patents, it also dealt with an "Agreement to limit advertising to different ***geographical*** regions." 53 F.3d 825, 828 (7th Cir. 1995) (emphasis added). It is undisputed that "AbbVie and the biosimilar Defendants did not agree that ***any*** market would be 'reserve[d]' for the biosimilar Defendants." Defs. Br. 28-29. And while the agreement in *Blackburn* was of "infinite duration," 53 F.3d at 828, the biosimilar Defendants can enter the U.S. market on dates certain prior to patent expiration. Plaintiffs' theory would lead to the conclusion that ***every*** patent settlement in which the parties agree on a compromise, future entry date in the United States (as the Supreme Court

permits in *Actavis*) could be challenged as a *per se* unlawful "market allocation" agreement if that date is not the same as another jurisdiction. No case supports that extraordinary theory.

Finally, ***none*** of Plaintiffs' other cases or Areeda & Hovenkamp ¶ 2030c involves patents or temporal limits. In *Garot Anderson Agencies v. Blue Cross & Blue Shield*, Blue Cross "agreed to stay out of," and "remove[d] [itself] from," Illinois. 1993 WL 78756, at *11 (N.D. Ill. Feb. 26, 1993). Whereas that agreement "foreclosed access to a territory" where Blue Cross's participation was lawful, *id.*, AbbVie simply declined to open until 2023 a territory (the United States) in which unlicensed participation is ***not*** lawful because of its patents. Plaintiffs cannot dispute that if Health Care (the other party to the agreement in *Garot*) held a patent, there would be nothing unlawful about it selling in both Wisconsin and Illinois but limiting Blue Cross to Wisconsin. That same logic applies for *United States v. Topco Associates*, 405 U.S. 596 (1972). If Topco held a patent on grocery products and entered into agreements stating that "[n]o [licensee] may sell these products outside the territory in which it is licensed," *id.* at 602, it would not be an unlawful market division, but instead Topco merely exercising its right to "carv[e] up the United States among its licensees." *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1305 (11th Cir. 2003).[7]

III. PLAINTIFFS FAIL TO PLEAD ANTITRUST INJURY

Lack of antitrust injury is a separate basis for dismissal. Plaintiffs do not allege facts that "'but for' the violation, the injury would not have occurred." *Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 998 F.2d 391, 395 (7th Cir. 1993). They also fail to recognize that courts

[7] Plaintiffs' claim that "defendants misread several authorities," Opp. 33, does not hold up. The *Palmer* Court reached beyond the facts of the case to explain what constitutes unlawful market division, yet even the Court's hypothetical required mutual exclusivity. *See* 498 U.S. at 49-50. That the contours of the rule recited in *In re Dealer Management Systems* were not tested on dismissal does not mean that the ***legal rule*** is not good law and cannot be applied in other cases. 362 F. Supp. 3d 477, 492-93 (N.D. Ill. 2019). Finally, that the plaintiffs in *Laumann* stated a claim based on "vertical agreements" that were "***essential*** to the horizontal market divisions" is irrelevant, because Plaintiffs do not allege vertical agreements here. *See* 907 F. Supp. 2d 465, 487-88 (S.D.N.Y. 2012) (emphasis added).

assess antitrust injury on a claim-by-claim basis. *See Appraisers Coal. v. Appraisal Inst.*, 1999 WL 89663, at *1 (N.D. Ill. Feb. 12, 1999) (antitrust injury is "an element of every antitrust claim"). Thus, for Counts I-IV, factual allegations must support injury from ***only*** the settlements, and for Counts V-VI, from ***only*** the "too many" patents. The Complaint fails this standard.

Plaintiffs now offer two new theories. First, they posit that the biosimilar Defendants could have prevailed in their patent litigation against AbbVie before the agreed entry dates. Opp. 48-50. Second, Plaintiffs claim that the biosimilars could have negotiated hypothetical alternative settlements providing for even earlier entry. *Id*. 46-48. Neither theory is supported by the allegations in the Complaint, and neither is sufficient to establish injury as a matter of law.

A. Plaintiffs' Litigation Theory Fails

Plaintiffs contend that they have pleaded antitrust injury for both their "too many" patents and settlement theories because "one of the biosimilars *could have* prevailed in patent litigation." Opp. 48. But "could have" is not the law: Plaintiffs must allege that, but for AbbVie's patents (Counts V-VI), and separately, but for the settlements (Counts I-IV), the alleged "injury ***would not*** have occurred." *Greater Rockford*, 998 F.2d at 395 (emphasis added). "Could have" connotes mere possibility, not plausibility. *Iqbal*, 556 U.S. at 678. Because Plaintiffs do not allege that any biosimilar "would have" overcome AbbVie's patents, dismissal is required.

In any event, injury is lacking even under the erroneous "could have" standard. For the monopoly claims, Plaintiffs assert a biosimilar could have prevailed in litigation because AbbVie's patents are weak. Opp. 48-50. But Plaintiffs do not contend that ***all*** AbbVie patents are invalid; the Complaint addresses only "several dozen" of the 100+ patents. *Id.* at 51. As *Terazosin* makes clear, any ***one*** of those is sufficient to defeat antitrust injury—just a single valid patent can preclude market entry. 335 F. Supp. 2d at 1369; *see* Defs. Br. 35. Plaintiffs attempt to distinguish *Terazosin* on *Noerr–Pennington* grounds, Opp. 52, but not only are Plaintiffs wrong about the immunity

standard, *see supra* pp. 5-8, they are mistaken that antitrust injury depends on it. "***Every*** private antitrust plaintiff" must show injury, regardless of whether petitioning conduct is at issue. *Energy Conversion Devices Liquidation Tr. v. Trina Solar Ltd.*, 833 F.3d 680, 689 (6th Cir. 2016) (emphasis added).[8] Plaintiffs also argue that they "have not pleaded, and no court or proceeding has found, that any of [AbbVie's] patents were valid." Opp. 49. But, regardless of the allegations, AbbVie's patents are presumed valid by statute. 35 U.S.C. § 282(a).

Moreover, Plaintiffs' litigation theory fails because the Complaint alleges no facts to show that litigation between AbbVie and the biosimilars could have resolved before 2023, regardless of the outcome. Plaintiffs cite 2019 and 2020 trial dates for Amgen and Boehringer, Opp. 50, but these were for the first phase of litigation only, *see* Dkt. #125 at 2-3. The BPCIA allows AbbVie to assert ***other*** patents in ***subsequent*** suits. Plaintiffs admit this, conceding "additional patents ***need[ ] to be addressed*** in a second phase ***before a biosimilar could launch***." *Id*. at 29 (emphases added). Notably, Plaintiffs do not allege that later suits (and appeals) could have concluded before the negotiated dates. These failures preclude a claim of injury from AbbVie's patents.

The allegations also belie a claim of injury from the settlements. For Counts I-IV, Plaintiffs must plead facts showing injury flowing from the settlements—the alleged unlawful conduct—and ***not*** from the alleged "thicket." *See Midwest Gas v. Ind. Gas Co.*, 317 F.3d 703, 711-14 (7th Cir. 2003). Plaintiffs plead the ***opposite***, alleging that AbbVie's patents were "impassable," and that "even if" a company could "parse through the morass of patents" and then litigate them, "it would not obtain a final judgment for many years," Compl. ¶¶ 9, 87. Those allegations doom Plaintiffs' claim of injury from the settlements and reflect a fundamental problem in the Complaint.

[8] Plaintiffs cite *In re Thalomid & Revlimid Antitrust Litigation*, 2015 WL 9589217 (D.N.J. Oct. 29, 2015), to argue that they need not challenge all patents. Opp. 51. But in that case, unlike here, the plaintiffs did challenge all of the patents that could have been asserted. *See* Dkt. 20-1 at 15, No. 2:14-cv-6997 (noting that the complaint alleges *Walker Fraud* or sham assertion as to six patents and invalidity as to all others).

B. Plaintiffs' Alternative Settlement Theory Fails

Plaintiffs also offer a speculative "alternative settlement" theory, under which the Court should assume that the biosimilars "would have negotiated earlier entry dates in the United States" if not for the European licenses. Opp. 46-47. But this new "claim for an injury deriving from the failure to reach a hypothetical procompetitive different agreement is nothing but speculation" and cannot survive dismissal. *Kroger*, 701 F. Supp. 2d at 957 (dismissing § 1 claim for lack of injury).[9]

This "alternative settlement" theory is also implausible as a matter of law. With respect to the thicket claims, Plaintiffs allege that if not for AbbVie's patents, the biosimilars would have had a "stronger bargaining position and would have negotiated an earlier entry date." Opp. 47. But Plaintiffs do not dispute that AbbVie prevailed in 13 of 20 IPRs, Defs. Br. 6-7, nor that the standard for instituting IPR (reasonable likelihood), 35 U.S.C. § 314(a), is far less stringent than the standard for invalidating a patent at trial (clear and convincing), *Microsoft v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). The more IPR challenges that AbbVie's patents withstood, the ***stronger***—not weaker—AbbVie's negotiating position became, regardless of whether there were allegedly weak patents in its portfolio. Plaintiffs' leverage theory thus gets things exactly backwards.

All of this applies to the settlements too. It is not plausible that AbbVie would have settled on terms allowing the biosimilars to enter the marker earlier in light of its strong litigation position. Plaintiffs describe AbbVie's 100+ patents as "impassable," contend that "few if any companies could litigate all of AbbVie's patents," and argue that the litigation "process itself would delay biosimilars by many years." Compl. ¶¶ 9, 85; Opp. 7. Plaintiffs do not say how, in the face of these allegedly "impassable" and legally presumptively valid patents, any one of which could keep the biosimilars off the market, the biosimilars could have or would have secured an earlier entry

[9] Plaintiffs' use of *Actavis* to support their injury argument is puzzling. Opp. 52-53. *Actavis* was brought pursuant to the FTC Act under which, unlike here, "no showing of proximate cause is required." *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 764 (E.D. Pa. 2005), *aff'd*, 868 F.3d 132 (3d Cir. 2017).

date. The facts disprove any such notion. Neither Mylan nor Boehringer was able to negotiate an earlier U.S. entry date—in fact, negotiating dates ***later than*** Amgen and Samsung—even though they did not receive a European license or any other alleged payment.[10]

But the Court need not delve into the but-for world of alternative settlements, because what ***actually*** happened confirms that there is no injury here. Two biosimilars declined to even send the statutory notice that they planned to launch, despite having FDA approval for more than a year and there being no legal bar in their way. Defs. Br. 36-38. Plaintiffs offer no response to this.

IV. PLAINTIFFS' STATE LAW CLAIMS FAIL AS A MATTER OF LAW

Plaintiffs fail to refute that their state-law claims also must be dismissed. Plaintiffs concede that their antitrust and consumer protection claims in Counts II, IV, and VI should be dismissed if their federal claims are. Opp. 58. Plaintiffs' state claims also fail on several other grounds.

A. Plaintiffs' State Antitrust Law Claims Should Be Dismissed

Illinois. Only the Attorney General may sue on behalf of indirect purchasers. 740 Ill. Comp. Stat. § 10/7(2). Plaintiffs cite cases holding this prohibition is inapplicable, Opp. 57, but better-reasoned decisions view it as "intertwined" with substantive rights, Defs. Br. 41. *Shady Grove Ortho v. Allstate Insurance Co.*, 559 U.S. 393 (2010), is not contrary. Opp. 57. There, Rule 23 trumped a ***general*** class action bar, *In re Wellbutrin XL Antitrust Litig.*, 756 F. Supp. 2d 670, 677 (E.D. Pa. 2010)—not the "substantive" Illinois one at issue here.

Utah. Utah permits recovery "only" by indirect purchasers who are "citizens or residents of Utah." *Opana*, 162 F. Supp. 3d at 725. No named plaintiff is a Utah citizen or resident. This is a pleading—not class certification—issue. *See id.* at 704; Opp. 57-58. Nor can an absent putative class member who is a Utahn confer standing. Opp. 58. "[A]t least one [Utahn] [must]

[10] This distinguishes *Opana*, where the brand company settled with other generics without reverse-payment terms but ***with*** earlier entry dates. *See* Dkt. #132-1 in No. 1:14-cv-10150 (N.D. Ill. Sept. 4, 2015); Dkt. #102 at ¶¶ 108, 202 in No. 1:14-cv-10150 (N.D. Ill. May 4, 2015).

be a named plaintiff." *In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 419 (D.N.J. 2018).

Nexus States. Plaintiffs contend they adequately pleaded claims in Mississippi, North Carolina, Tennessee, Wisconsin, and D.C. because consumers were "deprived of the opportunity to purchase less-expensive biosimilars." Opp. 54. But these states require that conduct occur in, or have a substantial effect within, the state. Defs. Br. 39-40.[11] "[I]nflated prices are not sufficient," *Dealer Mgmt.*, 362 F. Supp. at 549 (N.C.), and effects "other than the purchase" are necessary, *In re Vitamins Antitrust Litig.*, 2001 WL 849928, at *6 (D.D.C. Apr. 11, 2001) (Tenn.).

B. Plaintiffs' Consumer Protection Claims Should Be Dismissed

Plaintiffs contend that their Count VII claims are "distinct" from their antitrust claims and should not rise and fall with them. Opp. 58. But apart from that conclusory assertion, Plaintiffs never explain ***how*** they are different. Plaintiffs contend that dismissal would "limit the scope of consumer protection statutes," Opp. 59, but dismissal is a matter of sufficient pleading—not salutary policy—and the allegations in Count VII come up well short of Rule 8's standard.

Plaintiffs argue that Paragraphs 310-15 "specify" how AbbVie's conduct is unconscionable and unfair, Opp. 60, but the allegations (including ¶¶ 309-406, *see* Opp. 61) are no more plausible than those dismissed in *Aggrenox* and *Opana*—they merely recite legal conclusions. *Iqbal*, 556 U.S. at 679; *e.g.*, Compl. ¶¶ 340, 347, 348. "While legal conclusions can provide [a] framework ... they must be supported by factual allegations." *Iqbal*, 556 U.S. at 679. The Count VII claims are not, and should be dismissed. *See, e.g.*, *Bonte v. U.S. Bank, N.A.*, 624 F.3d 461, 465 (7th Cir. 2010) ("[W]e are not 'bound to accept as true a legal conclusion couched as a factual allegation.'").

CONCLUSION

The Consolidated Complaint should be dismissed with prejudice in its entirety.

[11] Plaintiffs contest Tennessee's nexus requirement, but *In re New Motor Vehicles Canadian Export Antitrust Litigation* confirms that the challenged conduct must "*substantially* affect[ ] commerce within [the] state." 350 F. Supp. 2d 160, 173-74 (D. Maine 2004).

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CERTIFICATE OF SERVICE

I certify that on December 20, 2019, I filed the foregoing Reply Brief in Support of Defendants' Motion to Dismiss using the Court's electronic CASE filing system. Notice of this filing will be transmitted to all counsel of record who are registered users of the Court's electronic case filing system.

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