UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

In re

GLUMETZA ANTITRUST LITIGATION.

No. C 19-05822 WHA
No. C 19-06138 WHA
No. C 19-06839 WHA
No. C 19-07843 WHA
No. C 19-08155 WHA
No. C 20-01198 WHA
No. C 20-05251 WHA

(Consolidated)

This Document Relates to:

DIRECT PURCHASER ACTIONS.

ORDER CERTIFYING CLASS

INTRODUCTION

In this antitrust action arising from an alleged reverse-payment settlement of a patent infringement suit between brand and generic marketers of the diabetes drug Glumetza, direct purchaser plaintiffs move for class certification. Common issues predominate, the putative class's market-impact and damages models adequately reflect the theory of liability, and any assumptions underlying the model either go to the heart of the merits or can be modified to account for a range of jury determinations. A class is **CERTIFIED**.

STATEMENT

A prior order details this case (Dkt. No. 188 *as amended* Dkt. No. 204). *In re Glumetza Antitrust Litigation*, ___ F. Supp. 3d ___, 2020 WL 1066934 (N.D. Cal. Mar. 5, 2020). But the essence bears restating. This case arises from a perversion of the patent and pharmaceutical-regulatory framework. *See generally* 35 U.S.C. § 156 *et seq.*, 21 U.S.C. § 301 *et seq.* The Hatch-Waxman Act implements a network of incentives to encourage faster introduction of low-cost generics into the pharmaceutical market, yet still drive new drug development. To

ease FDA approval, generic manufacturers may file an Abbreviated New Drug Application to piggyback on the approval process for the underlying brand drug. *See FTC v. Actavis*, 570 U.S. 136, 142 (2013); 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv).

Patents covering the brand drug can still spoil the fun, though. To gain approval, an ANDA applicant must certify to the FDA that no brand patents block the generic drug's market entry. If the brand holds live patents, for example, the generic must file a "Paragraph IV certification" of noninfringement or invalidity. Even so, if the brand manufacturer promptly sues for infringement, the FDA can't approve the generic for 30 months (or until the end of the suit, whichever comes first). *Actavis*, 570 U.S. at 143; 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)–(IV), (5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

The Hatch-Waxman scheme encourages patent-challenge certifications by granting 180 days of generic market exclusivity to the first generic to file such an application. If this "first filer" wins the infringement suit and markets, it gets 180 days to compete *alone* with the brand drug, meaning the FDA can't approve any other generics during that time. This can be "worth several hundred million dollars" to the generic manufacturer and outweigh the risk of infringement suit. *Actavis*, 570 U.S. at 143–44; 21 U.S.C. § 355(j)(5)(B)(iv). But this 180-day exclusivity period doesn't stop the brand manufacturer from marketing an "authorized generic" to recoup some of those millions. *See Teva Pharm. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005). Moreover, the first filer can forfeit the 180-day exclusivity if it stalls too long. 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa), (iii).

This scheme is supposed to get us faster, cheaper generic drugs. But the industry found a way to do the opposite. Sometimes a brand drug manufacturer sues an ANDA filer, and the *brand manufacturer* pays the generic to settle. In exchange, the first filer generic manufacturer agrees to stay off the market for a few years. Instead of expedited generic entry, the brand maintains its monopoly and cuts the supposed-generic a share of the profits. In 2013, the United States Supreme Court found that these "pay for delay" schemes can violate federal antitrust law. *Actavis*, 570 U.S. at 158–60.

Our putative class alleges such a scheme involving the diabetes medication Glumetza. But instead of a cash payment, our brand manufacturer gave something else of value, a virtual guarantee that our generic manufacturer would face no generic competition (authorized or otherwise) for at least a year after its belated market entry. This allowed the brand manufacturer to then raise the price of pills from $5.72 to over $51 each.

Some iteration of defendant brand manufacturer Bausch Health Companies Inc. has marketed Glumetza since 2005. In July 2009, defendant generic manufacturers Lupin Pharmaceuticals, Inc. and Lupin Ltd. filed an ANDA to market generic versions of Glumetza and certified noninfringement or invalidity against the four relevant patents: U.S. Patent Nos. 6,340,475; 6,635,280; 6,488,962; and 6,723,340. Assertio Therapeutics, Inc. (then owner of Glumetza marketing) sued Lupin for patent infringement in November 2009, triggering the 30-month stay against FDA approval. When the FDA tentatively approved the ANDA in January 2012 (meaning Lupin could market its generic but for the 30-month stay), Assertio and others involved in Glumetza marketing promptly settled with Lupin. *See Depomed, Inc. v. Lupin Pharms., Inc.*, No. C 09-05587 PJH, Dkt. No. 152 (N.D. Cal. Mar. 27, 2012).

Under the settlement, Lupin agreed to walk away, leave the patents alone, and *not* market a generic Glumetza for four years, until February 2016. In return, Assertio and Santarus promised no authorized generic would compete with Lupin for at least a year once its generic entered the market. The settlement also included two clauses to protect Lupin from other generic competition. The "most-favored-entry" clause expressly provided that if any other generic succeeded in marketing a generic Glumetza before February 2016, Lupin could market immediately. Then, the "most-favored-entry-plus" clause stated that Assertio and Santarus would not license any other generic Glumetza manufacturers until at least 180 days (though our facts seem to indicate a full year) following Lupin's market entry. These provisions undercut the incentive for any other generic manufacturer to enter the market before Lupin.

But only the first of these terms, that Lupin would not market until February 2016, made it into the parties' stipulated dismissal. Curiously, or as the putative class alleges, deliberately, Assertio, Santarus, and Lupin's "Consent Injunction and Dismissal Order" made no mention of

the no-authorized generic, the most-favored-entry, or the most-favored-entry-plus clauses. All of that was in a side agreement. Though defendants contend they put the world on notice of the no-authorized generic provision in July 2015, on these pleadings, defendants did not disclose the provision until February 2016. *Glumetza*, 2020 WL 1066934 at *7.

Apparently the scheme worked. No other generic manufacturers marketed generic Glumetza until well after Lupin. Sun Pharmaceuticals tried, filing its ANDA in May 2011. Asssertio and Santarus promptly sued and a January 2013 settlement allegedly kept Sun's generic off the market until August 2016. Watson Pharmaceuticals also tried, filing its ANDA in March 2012. Another prompt lawsuit from Assertio and Santarus resulted in a November 2013 settlement allegedly keeping Watson's generic off the market also until August 2016. Ultimately, Sun and Watson (by then Teva Pharmaceutical Industries Ltd.) didn't market their generic Glumetzas until mid-2017.

In the meantime, Assertio and Santarus milked their monopoly for all it was worth. After $150 million in Glumetza sales in 2012, defendant Salix Pharmaceuticals bought Santarus for $2.6 billion in November 2013, and Bausch paid $14.5 billion for Salix in April 2015. *Then, Bausch hiked the price of Glumetza tablets by about 800 percent over the first half of 2015. A 500mg tablet, $5.72 in February, skyrocketed to $51 in July. A 1000mg tablet jumped from $12 to $111*. Glumetza produced $145 million in the first half of 2015. Bausch reaped *$818 million* from its captive prescription base in the second half.

It appears prices have never recovered. In February 2016, Lupin joined in the bonanza, charging $44 for each 500 mg tablet of Glumetza. Even after Bausch's authorized generic entered the market in February 2016 and Teva and Sun's generics joined in May and July 2017, a 500mg tablet still cost $16.

Plaintiffs started suing in August 2019. Ultimately, twelve cases by both direct and indirect purchasers arrived before the undersigned. A March 5 order largely denied defendants' motions to dismiss the direct purchasers but granted the motions in part against the indirect purchasers, who all subsequently dismissed (Dkt. No. 188). The remaining direct purchasers come in two groups: (1) the direct-purchaser plaintiffs and putative class (Consol. Amd.

Compl., Dkt. No. 53); and (2) the retailer plaintiffs (Walgreen Compl., Dkt. No. 162; Rite Aid Compl., Dkt. No. 163). Plaintiffs in both groups sue as assignees of other absent direct purchasers.

Direct purchaser plaintiffs now seek certification of a Rule 23(b)(3) class:

> All persons or entities in the United States and its territories who directly purchased Glumetza or generic Glumetza from a defendant from May 6, 2012, until the effects of the defendants' conduct ceased.

Defendants oppose. This order follows full briefing and a hearing (held telephonically due to COVID-19).

ANALYSIS

Numerosity of members, commonality of issues, typicality and adequacy of representatives, and one requirement of Rule 23(b) guard the door to class certification. *Abdullah v. U.S. Sec. Assocs., Inc.*, 731 F.3d 952, 956–57 (9th Cir. 2013). "[Q]uestions of law or fact common to class members [must] predominate over questions affecting only individual members" in direct purchaser plaintiffs' proposed Rule 23(b)(3) class, which must also be the superior method "for fairly and efficiently adjudicating" this case. Rule 23 doesn't set forth a mere pleading standard; it demands rigor. A putative class must affirmatively demonstrate that it "*in fact*" meets these prerequisites. *Comcast v. Behrend*, 569 U.S. 27, 33 (2013).

1. COMMONALITY AND PREDOMINANCE.

Commonality requires "questions of law or fact common to the class." Rule 23(a)(2). "A common contention need not be one that will be answered, on the merits, in favor of the class. It only must be of such nature that it is capable of classwide resolution." *Alcantar v. Hobart Serv.*, 800 F.3d 1047, 1053 (9th Cir. 2015) (citation and quotation omitted). There need only be "a single significant question of law or fact." *Stockwell v. City & Cty. of San Francisco*, 749 F.3d 1107, 1111 (9th Cir. 2014).

Superseding commonality, predominance under Rule 23(b)(3) asks whether a putative class is "sufficiently cohesive to warrant adjudication by representation." Predominant questions makeup "a significant aspect of the case" and clearly justify "handling the dispute on

a representative rather than on an individual basis." Predominance isn't a counting game, though. "Rather, more important questions apt to drive the resolution of the litigation" carry greater weight than less significant individualized questions. So, "even if just one common question predominates, 'the action may be considered proper under Rule 23(b)(3) even though other important matters will have to be tried separately.'" *In re Hyundai & Kia Fuel Econ. Litig.*, 926 F.3d 539, 557 (9th Cir. 2019) (en banc) (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. ___, 136 S. Ct. 1036, 1045 (2016)).

"Merits questions may be considered to the extent — but only to the extent — that they are relevant to determining whether" the putative class has satisfied the requirements for class certification. *Amgen Inc. v. Connecticut Retirement Plans & Trust Funds*, 568 U.S. 455, 465–66 (2013). That being said, deciding whether common evidence drives class claims necessarily asks what law governs. So our "assessment of predominance begins, of course, with the elements of the underlying cause of action." *Walker v. Life Ins. Co. of the Southwest*, 953 F.3d 624, 630 (9th Cir. 2020) (quotation omitted). "To establish an antitrust claim, plaintiffs typically must prove (1) a violation of the antitrust laws, (2) an injury they suffered as a result of that violation, and (3) an estimated measure of damages." *In re New Motor Vehicles Canadian Export Antitrust Litig.*, 522 F.3d 6, 19 n. 18 (1st Cir. 2008)).

A. ANTITRUST VIOLATION.

Our class invokes both Sections 1 and 2 of the Sherman Act. "Bearing firmly in mind," however, that Rule 23(b)(3) turns "on the predominance of common *questions*," we recall that the question here — one step removed from proof of defendants' unlawful scheme — remains whether that *proof* comes common to the class, or whether we will have to search for it class member by class member. *See Amgen*, 568 U.S. at 466. The Supreme Court has observed that antitrust cases "readily" meet the predominance requirement. *See Amchem Prods. v. Windsor*, 521 U.S. 591, 625 (1997). The underlying purpose of antitrust, to "safeguard general competitive conditions, rather than to protect specific competitors," illustrates why. The violation turns on *defendants'* conduct and intent along with the effect on the market, *not* on

individual class members. *See Alaska Airlines v. United Airlines*, 948 F.2d 536, 540 (9th Cir. 1991).

A Section 1 restraint claim requires (1) a contract, combination, or conspiracy that (2) unreasonably restrains (3) interstate commerce. An unreasonable restraint comes either as a *per se* violation ("when surrounding circumstances make the likelihood of anticompetitive conduct so great as to render unjustified further examination") or a violation of the rule of reason, meaning the "restraint's harm to competition outweighs its procompetitive effects." *NCAA v. Bd. of Regents of Univ. Okla.*, 468 U.S. 85, 103–04 (1984); *Tanaka v. Univ. of S. Cal.*, 252 F.3d 1059, 1063 (9th Cir. 2001). In pharmaceutical reverse payment cases, such as this one, the Supreme Court has directed us to apply the rule of reason, explaining that:

> [T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.

Actavis, 570 U.S. at 158–59. Notice then that the illegality of defendants' scheme turns on details of the payment and defendants' purposes — evidence common to every purchaser.

Section 2 monopolization claims readily lend themselves to common evidence. They require "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Alaska Airlines v. United Airlines*, 948 F.2d 536, 541 (9th Cir. 1991) (quoting *Aspen Skiing Co. v. Aspen Highlands Skiing Co.*, 472 U.S. 585, 596 n. 19 (1985)). So, the state of the market and defendants' use and maintenance of monopoly power, as opposed to individual plaintiff's conduct, drives the claim.

The class confirms its intent to prove the antitrust violation by common proof. In the alleged conspiracy, the generic-drug manufacturer joined, maintained, and partook in the spoils of the brand monopoly. After Assertio and Santarus sued Lupin for seeking FDA approval to market a generic form of Glumetza, they all settled in February 2012. Assertio and Santarus saved their patents, preserved their monopoly from generic competition until February 2016,

and enjoyed free rein to hike the drug price by nearly 800 percent — from $5.72 to $51 for a single 500mg tablet — in the first half of 2015. Lupin had to sit tight at first. But, in February 2016 — free of other generic or authorized generic competition for at least one year — it would hop aboard the cash-cow, pricing its generic slightly below the still-wildly-overpriced brand drug. Though prices would drop as more generics entered the market, due to defendants' scheme, even today brand and generic Glumetza prices have not yet dropped to pre-hike levels. That is to say that in the class's telling, defendants wildly succeeded in their antitrust violation, suppressing competition and inflating prices, before we even mention individual class members or, for that matter, the background — the potentially millions of diabetic Americans, their livelihoods dependent upon the prescription drug, faced with the grim choice to either pony up the cash or else. *See Alaska Airlines*, 948 F.2d at 540.

Defendants wisely do not contest that common issues predominate the underlying antitrust violation. Instead, they save their objections for the class's showing of injury and the measure of damages.

B. ANTITRUST IMPACT.

Antitrust impact is "the causal link between the antitrust violation and the damages sought by plaintiffs." The class must provide "some means of determining that each member of the class was in fact injured." *New Motor Vehicles*, 522 F.3d at 19 n. 18, 28. Yet the theory of impact must not only be closely tied to the theory of liability, it must be limited to it. *See Comcast*, 569 U.S. at 35. This follows from the notion that "the defendants cannot be held liable for damages beyond the injury they caused." *See In re Nexium Antitrust Litigation*, 777 F.3d 9, 18 (1st Cir. 2015). Put simply, a theory of liability (and, thus, class definition) that either catches too many uninjured putative class members, or ignores too many injured ones, likely misses the actual cause of the harm. In sum, then, the class "must be able to establish, predominantly with generalized evidence, that all (or nearly all) members of the class suffered damage as a result of [defendants'] alleged anti-competitive conduct." *In re Qualcomm Antitrust Litigation*, 328 F.R.D. 280, 299 (N.D. Cal. 2018). Faced with an expert in each corner, a court must engage with the testimony and resolve material disputes, "but only to the

extent" that they weigh on the requirements for certification. *See Ellis v. Costco*, 657 F.3d 970, 981–84 (9th Cir. 2011); *Amgen*, 568 U.S. at 465–66.

Here, the driving question remains "what did defendants' scheme do to the market?" Asking "which class members were swept up in scheme" poses a secondary question, which, though it often requires individualized inquiry, may still be answered predominantly by common drug sales data. The class offers the testimony of economist Dr. Jeffrey J. Leitzinger, Ph.D., who concludes, based upon the common evidence of economics literature, defendants' own market forecasts, and both defendants' and third-party brand and generic Glumetza sales data, that defendants' anticompetitive conduct inflicted overcharges on each putative class member.

Dr. Leitzinger explains that economics literature reliably concludes generic drugs, as essentially-identical commodities, compete with the brand and with each other based on price, lowering prices. Generic drugs crash brand monopolies, entering the market at significant discounts. Studies show this discount increases over time (*and* as more generics enter the market) and quickly pervades the market as the generics capture the prescription base through permissive or (often, state or locally) mandated generic-substitution at the pharmacy. And, this generic market penetration increases over time. Atop that, some studies also found the brand prices themselves dropped in response to generic competition (Leitzinger Decl., Dkt. No. 246-2, at ¶¶ 19–21, 30–36, 47). *See, e.g.*, *New York ex rel. Schneiderman v. Actavis*, 787 F.3d 638, 644–45 (2d Cir. 2015) (brief survey of state substitution laws).

To counter this threat, brands often market an "authorized generic" to recapture some of the market. But, of course, the authorized generic acts like a regular generic, driving greater generic discounts and market capture. So, even though the authorized generic recaptures brand revenue, it still aids competition (*id.* at ¶¶ 22–24).

Our defendants certainly expected as much. Dr. Leitzinger reports, from careful review of their own documents, both *Bausch and Lupin expected the coming generics to slash prices and capture nearly the entire Glumetza market after a couple of years*. Reality confirmed these expectations. Before Lupin joined the market, Santarus, Salix, and then Bausch sold Glumetza

at an average discount of 13 percent off the list price. In February 2016, Lupin joined the market at a 47 percent average discount. Bausch's February 2017 authorized generic then drove the average generic discount to 62 percent and its own brand discount to 18 percent. And, Teva and Sun's mid-2017 entry drove the generic discount to 93 percent. By 2018, generics had captured 80 percent of the Glumetza prescription base (*id.* at ¶¶ 37–38, 40).

Defendants stalled these discounts by inducing Lupin to delay entry by four years. By February of 2016, the market should have enjoyed years of Lupin's generic and an authorized generic along with the accompanying (and ever increasing) generic discount and market penetration. Instead, putative class members suffered three and a half years without the discount — and indeed, due to defendants' further anticompetitive conduct, an 800 percent price *hike* in 2015. Simply, Dr. Leitzinger concludes, "conduct which delays or limits generic competition . . . inflate[s] prices broadly across the brand prescription base." More important for the present purposes, however, Dr. Leitzinger also stresses that his model relies only upon the common evidence of, as noted, economic literature, defendants' own forecasts, and actual sales data (*id.* at ¶¶ 21, 26–29, 36, 45–51).

Dr. Leitzinger finally explains that three forms of overcharge span the class, beginning with lost generic conversion. The more than eighty percent of Glumetza prescriptions that should have been filled with the generic, weren't. Each of the putative class members served a sufficient population, so each almost certainly lost out on generic substitution of at least one prescription. Every lost generic substitution meant an overcharge. Beneath that, simply due to suppressed competition, each brand and generic purchase also carried an overcharge (*id.* at ¶¶ 54–62).

Defendants try to undercut the Dr. Leitzinger's factual assumptions. Actually, they start by attacking Dr. Leitzinger's reliance on any factual assumptions at all, charging him with "offer[ing] no evidence for any of his assumptions at all." But *of course* Dr. Leitzinger assumes the circumstances in which he models the impact of defendants' behavior. Recall, antitrust impact is "the causal link between the antitrust violation and the damages." *New Motor Vehicles*, 522 F.3d at 19 no. 18. Evaluating whether common issues predominate antitrust

impact requires us to assume class counsel will otherwise prove (by common evidence) the antitrust violation at trial. So, Dr. Leitzinger assumes (as counsel directed): (i) Lupin would have entered the market (perhaps even "at risk") in May 2012; (ii) Santarus would have promptly marketed an authorized generic; and (iii) the 2015 price hikes would not have occurred.

In response, defendants primarily contend that all these circumstances must be proven by a preponderance, else they undermine class cohesion. These objections test the merits and run headlong into *Amgen*. There, the United States Supreme Court explained that in securities fraud the materiality of a misrepresentation — an admittedly essential step in the plaintiffs' ability to prove classwide reliance on a misrepresentation — did not need to be proven at class certification because, first, materiality turned on an objective (and thus, collective) standard and, more importantly, that materiality comprised an essential element of the case. Individual questions would not predominate absent materiality. Rather, that class would lose. 568 U.S. at 466–70. The Supreme Court recently reaffirmed this understanding, explaining that where "the concern about the proposed class is not that it exhibits some fatal dissimilarity but, rather, a fatal similarity — [an alleged] failure of proof as to an element of the plaintiffs' cause of action — courts should engage that question as a matter of summary judgment, not class certification." *Tyson*, 136 S. Ct. at 1047.

Dr. Leitzinger's factual assumptions satisfy both prongs here because each comprises a scenario that the class alleges would have occurred but-for distinct portions of defendants' anticompetitive conduct. This conduct will be provable by common evidence at trial, as discussed above. More importantly, though, the class's failure on any ground does not result in rampant individual questions. Instead, that mode of harm drops out of the case.

Defendants argue extensively that Lupin would not have launched around May 2012, much less "at risk," because it expected to lose, and in fact would have lost, the patent suit. Even if it did launch "at risk," defendants say, Lupin's generic would have been pulled off the market promptly. In that scenario, defendants' expert Dr. Bruce Strombom concludes only a subset of the class would have been harmed. It remains to be seen how deep into the patent

weeds we will need to delve at summary judgment or at trial. *Actavis* itself indicates that "[i]t is normally not necessary to litigate patent validity" — and presumably also infringement — "to answer the antitrust question," because the lawfulness of the settlement turns on its purpose, effect, and (if needed) justification. *See* 570 U.S. 157–59. This follows somewhat from the fact that courts remedy analogous anticompetitive behavior, patent misuse, by holding a patent unenforceable, a remedy unnecessary unless the patent is valid and infringed. *See Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1328 (Fed. Cir. 2010). Then again, given the present analysis turns so heavily on defendants' intent, some scrutiny of validity and infringement, or at least the boundaries of the parties' reasonable beliefs about them, may be required. *Cf. Alaska Airlines*, 948 F.2d at 540; *Aspen*, 472 U.S. 602–03. But all that will be decided for the class at summary judgment or trial.

The point here is that defendants raise the patent merits to change the but-for scenario and jump ahead to the impact analysis, forgetting to reevaluate the threshold question of the antitrust violation. The class's allegations of an unlawful reverse settlement depend on Lupin's February 2016 market entry being delayed from around mid-2012. If the jury finds Lupin's generic Glumetza *did* infringe valid patents, or perhaps at least that both parties honestly believed it did, then negotiations would have started with a late 2016, or even 2020 (after the last patent expired), market entry. In that case, the settlement ceases to be anticompetitive. The class doesn't just break down — the entire class loses (Aug. 6 Hrg. Tr., Dkt. No. 346, at 15). *See Actavis*, 570 U.S. 136; *Amgen*, 568 U.S. at 466–70. So, the patent merits and the assumption that Lupin would have marketed early and successfully do not require proof at this stage.

Assuming, then, that the jury does find the 2012 settlement agreement unlawful, it still need not accept all of the allegations. For example, if it finds that Santarus would not have launched an authorized generic anyway, then that circumstance would have applied across the board, to all class members. Moreover, Dr. Leitzinger discusses an authorized generic's influence on price discounts and generic market penetration as a discrete factor. That means he can easily remove those effects from the model to suit the finding, just as *Comcast* requires (Leitzinger Decl. at ¶¶ 61, 69, 70 n. 85). Defendants do not otherwise explain how an honest

decision not to market an authorized generic would yield rampant individual questions (Dkt. No. 262-5 at 14).

So too for the 2015 price hikes. We have excellent counsel on both sides in this case and it will be most engaging to see how counsel argue that the 800 percent price hike served competition. If the argument works, though, then that conduct would not be an antitrust violation, to *all* class members. And, again, instead of defendants explaining how this would undermine the model, Dr. Leitzinger explains he could easily remove that assumption from it (Leitzinger Decl. at ¶ 70 at n. 86).

So, rather than just assuming the class's cohesion, Dr. Leitzinger simply assumes (as he must) that the class will prove the first portion of its case at trial. If it doesn't, the harms don't become individualized. Instead, the class will either have lost the case, or the harms will simply fall away entirely and Dr. Leitzinger will remove them from his model. Defendants' merits arguments will have to wait for summary judgment or our jury. Thus, this order does not address the class's evidence of causation submitted in reply and defendants' objection to consideration of that evidence is denied as moot.

Defendants' invoke *In re Lamictal Direct Purchaser Antitrust Litigation*, in which the Court of Appeals for the Third Circuit vacated a class certification order for inadequately addressing "a market characterized by individual negotiations and a discounted-brand competition strategy." That decision, however, turned on the "nuance in the anti-epilepsy drug market." GlaxoSmithKline, the brand manufacturer, believed an authorized generic would not compete effectively with Teva's anticipated generic given doctors' particular reluctance to switch patients' anti-epilepsy medications. Glaxo thus planned to compete with Teva's generic based on price in an aggressive individual discount and rebate campaign with pharmacies. Teva learned of this plan and dropped its generic price even lower before launch. These unique pricing facts do not apply here. *See* 957 F.3d 184, 189–90, 192 (3d Cir. 2020); *see also In re Zetia (Ezetimibe) Antitrust Litigation*, No. MD 18-02836 DEM, 2020 WL 3446895, *31 (E.D. Va. June 18, 2020) (Magistrate Judge Douglas E. Miller) (distinguishing *Lamictal* for same reason).

C. ESTIMATE OF DAMAGES.

Having proven a common mode of antitrust impact, we turn to the damages model. A putative class must "establish that damages are susceptible of measurement across the entire class." *Comcast*, 569 U.S. at 35. Yet "[a]ntitrust plaintiffs may satisfy the predominance requirement by using a model that estimates the damages attributable to the antitrust injury, even if more individualized determinations are needed later to allocate damages among class members." *In re Suboxone (Buprenorphine Hydrochlorine and Naloxone) Antitrust Lit.*, ___ F.3d ___, 2020 WL 4331523, at *4 (3d Cir. July 28, 2020). Indeed, our court of appeals has "repeatedly confirmed" that "the need for individual damages calculations does not, alone, defeat class certification." *Vaquero v. Ashley Furniture Indus.*, 824 F.3d 1150, 1155 (9th Cir. 2016). And as above, "a plaintiff's damages case must be consistent with its liability case, particularly with respect to the alleged anticompetitive effect of the violation." *Comcast*, 569 U.S. at 35.

Yet "[c]alculations need not be exact." *Ibid.* The Supreme Court has repeatedly explained that courts should afford plaintiffs relatively broad leeway in constructing a damages model — at least within the "just and reasonable inference[s] from the proof of defendants' wrongful acts and their tendency to injure plaintiffs' business." *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 264 (1946). The Supreme Court has more recently affirmed this understanding, explaining that "[t]he vagaries of the marketplace usually deny us sure knowledge of what plaintiff's situation would have been in the absence of the defendant's antitrust violation." *J. Truett Payne Co. v. Chrysler Motors Corp.*, 451 U.S. 557, 566 (1981). Plainly, we can't know exactly what would have happened in that but-for world; defendants saw to that.

Dr. Leitzinger calculates the aggregate class overcharge, the difference between what class members actually paid and what they should have paid, as a function of the volume of Glumetza (or generic) actually sold, the wholesale acquisition cost, the actual (brand or generic) price, and the brand discount, generic discount, and generic market penetration but for

defendants' conduct (Leitzinger Decl. at ¶¶ 63–65). Common evidence drives each of these values.

The volume and actual price of Glumetza are easy; Dr. Leitzinger just uses the actual numbers. For the wholesale acquisition cost, Dr. Leitzinger takes the actual value from 2015, just before the exorbitant 800 percent price hikes. And, for generic market penetration, Dr. Leitzinger takes the actual numbers from Lupin's market capture after it joined in 2016. He just applies that market penetration to 2012, when Lupin was supposed to (allegedly) enter the market. So too with the brand discount. Dr. Leitzinger simply takes the actual observed brand discount after each generic entered the market and, again, backcasts the data to a 2012 Lupin entry (*id.* at ¶¶ 66–68).

Calculating the generic discount takes a little more work, given Lupin joined in the conspiracy, knew it would face no authorized generic (indeed no generic competition at all) for the first year, and almost certainly priced accordingly. Thus, Dr. Leitzinger uses Lupin's actual discount as evidence, but he also factors in defendants' forecasts of generic pricing and data from earlier economic studies (*id.* at ¶ 69).

At this stage, Dr. Leitzinger estimates the total class overcharge at approximately $2.3 billion (*id.* at ¶ 73). He also provides some sample calculations, but we need not dig that deep. For now, it suffices that his model employs common data and applies class wide, even if allocation of the damages will require some individualized inquiry down the road. *Vaquero*, 824 F.3d at 1155. Defendants offer three general objections.

First, defendants broadly contest various inputs into Dr. Leitzinger's damages model. To start, we can quibble about the particular inputs for Dr. Leitzinger's model later. It will be for the jury to determine what exactly happened absent defendants' conduct. As another judge of this district has observed regarding similar critiques of, coincidentally, Dr. Leitzinger's earlier work, "[t]h[e]se disputes are not appropriately resolved at this juncture; that the experts dispute what the appropriate inputs should be does not undermine the approach or the reliability of [Dr.] Leitzinger's model." *See In re Lidoderm Antitrust Litigation*, No. MD 14-02521, 2017 WL

679367 at *12 (N.D. Cal. Feb. 21, 2017) (Judge William H. Orrick). Yet both of defendants' arguments on this front also contain their own defects.

Defendants contend Dr. Leitzinger's method of backcasting generic penetration and brand discounts "is unreliable because it fails to recognize the significant differences between the actual world and [Dr.] Leitzinger's assumed but-for world." *Bigelow* and *Chrysler* undercut this argument. It remains difficult, scratch that, impossible to know what would have happened absent defendants' unlawful conduct because, assuming the class wins, the unlawful scheme itself deprived us of that information. Estimates are, therefore, the only way to replay the film without the violation. Dr. Leitzinger puts forth a sound enough model and our jury will construct the but-for world, not with absolute precision, but with "just and reasonable estimate[s]." *See Bigelow*, 327 U.S. at 264–66; *Chrysler*, 451 U.S. at 565–67.

Defendants then object that Dr. Leitzinger's model improperly includes purchases by opt-out plaintiffs, exclusion of which will require individualized inquiries. Removing opt-out plaintiffs from the calculations may well require individualized inquiries, as most damages inquiries do. But that does not undermine class certification, particularly where the core-classwide model holds. Dr. Leitzinger explains that he can easily adapt his model to account for opt-out plaintiffs. More importantly, however, as Dr. Leitzinger notes, unless the opt-out plaintiffs drop their cases we're going to be calculating their damages anyway. So the modification to the class damages model will most likely involve subtracting whatever damages we calculate due to each opt-out plaintiff (Leitzinger Rebut. at ¶¶ 47–55). *See Vaquero*, 824 F.3d at 1155.

Second, defendants protest that Dr. Leitzinger ignores the post-initial-sale complexities of the pharmaceutical drug market. Both forms of this argument mistake the cognizable harm here, the overcharge. For one, defendants argue that Dr. Leitzinger fails to account for generic bypass. In the but-for world, so the argument goes, purchasers often bypass the wholesaler and buy directly from the generic manufacturer, so defendants' conduct actually *benefitted* the wholesaler. Before addressing this objection directly, it's worth noting that the decision cited to support this objection, *Valley Drug Co. v. Geneva Pharm.*, 350 F.3d 1181 (11th Cir. 2003), "has

been met with almost universal criticism." *In re Glumetza*, No. C 19-05822 WHA, Dkt. No. 305, 2020 WL 3498067 at *12 (N.D. Cal. June 29, 2020) (Magistrate Judge Robert M. Illman); *see also Braintree Labs. v. McKesson Corp.*, No. 11-80233 MISC JSW, 2011 WL 5025096 (N.D. Cal. Oct. 20, 2011) (Magistrate Judge Jacqueline Scott Corley). More importantly, however, defendants' argument incorrectly focuses on the wholesaler's later realized profit margin instead of the actual injury here, the *overcharge*. *Hanover Shoe v. United Shoe Mach. Corp.*, 392 U.S. 481, 489 (1968). Judge Curtis L. Collier of the Eastern District of Tennessee put it well:

> Defendant[s] ignore[] the fundamental import of *Hanover Shoe* and its progeny: a direct purchaser may recover the full amount of the overcharge, even if he is otherwise benefitted, because the antitrust injury occurs and is complete when the defendant[s] sell[] at the illegally high price. That is, the focus of the antitrust laws is limited to the anticompetitive sale. When Defendant[s] sold the [drug] to the wholesalers at an allegedly anticompetitive price, the injury was complete. The jury need not hear any more. True, to calculate damages the jury must consider what the cost of the drug would have been in the absence of an antitrust violation. But *Hanover Shoe* and *Illinois Brick* make clear that courts and juries will not be forced down the rabbit hole of hypothetical issues antitrust violators may raise to minimize their liability.

In re Skelaxin (Metaxalone) Antitrust Litigation, No. MD 12-02343 CLC, 2014 WL 2002887, *5 (E.D. Tenn. May 15, 2014) (quotations and citations omitted); *see also In re Niaspan Antitrust Litigation*, No. MD 13-02460 JED, 2015 WL 4197590, *1 (E.D. Pa. July 9, 2015) (Judge Jan E. DuBois) (quoting same).

Defendants also forget that the overcharge "arose at the time the extra charge was paid," regardless of whether the defendant later attempts to mitigate. *See Adams v. Mills*, 286 U.S. 397, 407 (1932). So, their argument that Dr. Leitzinger's damages model "does not reflect the many discounts and subsequent payments that must be accounted for to calculate the ultimate *net* price" falls flat. As the Court of Appeals for the First Circuit rejected the same argument in *Nexium*, "antitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset." 777 F.3d at 27; *see also Hawaii v. Standard Oil of Cal.*, 405 U.S. 251, 262 n. 14 (1972).

Third, defendants argue the Dr. Leitzinger cannot adjust his damages model to account for various putative class members what will be barred by the statute of limitations. Assuming they will be barred, Dr. Leitzinger nonetheless explains that those class members' damages can be easily removed from the calculation of class damages (Leitzinger Rebut. at ¶ 71). Moreover, this objection appears to misunderstand what the limitations period does here. Our court of appeals, when first applying fraudulent concealment to § 15b's four-year limitations period, rejected the abstract notion that the limitations period was "an inherent element of the right." The limitations period did not "expunge a cause of action, but rather . . . create[d] a uniform period throughout the entire nation for the commencement of suit." Simply, a limitations period does not mean that no harm has occurred, it merely marks where claims have grown "stale" and we no longer permit recovery. If defendants' conduct harmed the market as a whole, and the statute of limitations bars some actors but not others, Dr. Leitzinger's model should still account for *all* of the harm to all of the actors. We may, however, simply bar some of those putative class members from recovering if the statute of limitations applies. *See Westinghouse Elec. Corp. v. PG&E*, 326 F.2d 575, 579–80 (9th Cir. 1964).

2. TYPICALITY.

Typicality tests "whether other members have the same or similar injury, whether the action is based on conduct which is not unique to the named plaintiffs, and whether other class members have been injured by the same course of conduct." *Wolin v. Jaguar Land Rover N. Am.*, 617 F.3d 1168, 1175 (9th Cir. 2010).

Defendants says the named plaintiffs, assignees of other Glumetza purchasers, are atypical of the class. At the start, though, "an assignee stands in the shoes of his assignor, deriving the same but no greater rights and remedies than the assignor then possessed." *In re Loestrin 24 Fe Antitrust Litigation*, No. MD 13-02472 WES, 2019 WL 3214257 at *11 (D.R.I. July 2, 2019) (Judge William E. Smith) (quoting, ultimately, *Fox-Greenwald Sheet Metal Co. v. Markowitz Bros., Inc.*, 452 F.2d 1346, 1358 n. 69 (D.C. Cir. 1971)). For largely the same reasons the Court of Appeals for the Third Circuit has explained, also in the pharmaceutical-antitrust context at the class certification stage, that assignees take the claim for relief as their own and separate

right and should be treated as any other class member (absent impropriety in assignment). *See In re Modafinil Antitrust Litigation*, 837 F.3d 238, 251 (3d Cir. 2016). Assignee status alone here does not weigh against the named plaintiffs.

But, defendants contend, the assignments all cover different time periods. Surely putative class members seeking damages from different time periods will have inconsistent goals. Hardly. Regardless of the time period of an assignment or when a putative class member purchased Glumetza, the earlier defendants' generics entered the market, the earlier generic competition would have lowered prices for all. The earlier the entry, the greater the overcharge, the greater the damages. *See Loestrin*, 2019 WL 3214257 at *12.

Defendants insist, though, that the named plaintiffs didn't actually buy that much Glumetza compared to, say, the "Big Three wholesalers" who accounted for 82 percent of direct brand purchases and 71 percent of direct generic purchases. "Notably," defendants say, "none of them has filed suit." If defendants mean to imply their lawful conduct from this fact, they read too much from the large wholesalers' absence. Many factors drive a decision not to sue, including, as the Supreme Court has recognized, a wholesaler's "fear of disrupting relations with their suppliers." *See Illinois Brick*, 431 U.S. 720, 746 (1977). More importantly, that the remaining class members possess noticeably smaller recovery interests actually weighs *in favor* of the economies of class treatment, not against it. *See Lidoderm*, 2017 WL 679367 at *15.

Defendants finish with the argument that the assignments "are complex documents" which assign claims arising from certain portions of sales to different assignees. Tracing the assignments, they say, will be difficult. Maybe so, but no more difficult than we might already expect to calculate to ensure that all damages are no more than "just and reasonable estimate[s]" of the actual harm to each putative class member. *See Bigelow*, 327 U.S. at 264–66.

3. ADEQUACY.

Our court of appeals has explained that adequate representatives (1) have no conflicts of interest with other class members, and (2) will prosecute the action vigorously on behalf of the class. *Staton v. Boeing Co.*, 327 F.3d 938, 957 (9th Cir. 2003).

Defendants mainly contend that named plaintiffs have not diligently pursued this case and, thus, cannot adequately represent the class. For one example, defendants say that named plaintiffs have not adequately gathered relevant sales information from their wholesaler assignors. They cite one instance in February when wholesaler McKesson ignored a deficient subpoena from named plaintiff KPH, who then never followed up. Vagueness mars defendants' objection. Without detail sufficient to conclude that the class needs this information to diligently pursue its case, the failure to follow up on a discovery request means little.

For the other, defendants object to two instances of named plaintiffs' supplemental document production. Parties must conduct a reasonably comprehensive document search, not an absolutely comprehensive one. *See, e.g.*, SUPPLEMENTAL ORDER TO ORDER SETTING INITIAL CASE MANAGEMENT CONFERENCE ¶ 16. Relevant documents often appear in later, different searches and nonetheless require prompt, supplemental disclosure. Defendants neither contend that the named plaintiffs withheld documents nor that they conducted inadequate initial searches. Nothing here raised undercuts named plaintiffs' adequacy to represent the putative class.

Defendants also argue that named plaintiffs sue over their substantial assigned brand Glumetza purchases, but most of the class purchased only generic Glumetza. So, while named plaintiffs seek damages from *actual* sale overcharges, absent class members might prefer a damages model based primarily on all the generic purchases and resales they *never made* due to defendants' conduct. Maybe so. But our court of appeals is not alone in warning against denial of class certification on the basis of speculative conflicts. *See In re Online DVD-Rental Antitrust Litigation*, 779 F.3d 934, 942 (9th Cir. 2015); *Kohen v. Pacific Inv. Mgmt. Co.*, 571 F.3d 672, 680 (7th Cir. 2009). Should any absent class members prefer a different damages model, they remain free to opt-out of the class. *In re Niaspan Antitrust Litigation*, 397 F. Supp. 3d 668, 681 (E.D. Pa. 2019); *Lidoderm*, 2017 WL 679367 at *15.

4. SUPERIORITY.

Even if common questions predominate, a Rule 23(b)(3) class must be the superior method of adjudication, considering (among others):

(A) the class members' interests in individually controlling the prosecution or defense of separate actions;

(B) the extent and nature of any litigation concerning the controversy already begun by or against class members;

(C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and

(D) the likely difficulties in managing a class action.

Though complexities will surely arise, including some individualized questions, no inability to manage a class action manifests here. The finality of decision for all involved counsels in favor of concentrating this litigation in a single forum — indeed the class members came to that conclusion themselves by all filing here. No other cases arising from defendants' challenged conduct here remain before any other tribunal. All this, in conjunction with the predominance of common issues, establishes that a class action is the superior method of adjudicating this case.

It's also worth noting the simplicity of the proposed class definition: Glumetza purchasers from defendants since May 2012. If, given defendants' litany of arguments, more specific requirements become necessary, the class definition will remain manageable. So too, if specific populations appear within the class, subclasses may be certified to proceed.

Defendants contend that a class is not superior because the largest purchasers of Glumetza have elected to go it alone. As above, a larger number of smaller claims lend themselves to the economies of the class. Nevertheless, defendants also argue that class members seek, on average, treble damages of $28 million. So, their argument goes, the recovery will cover any legal fees and each putative class member can proceed individually with its own counsel, each, naturally, siphoning the potential recovery as though we're trying to recreate Dickens' *Bleak House*. A class remains superior here.

5. NUMEROSITY.

A class must be "so numerous that joinder of all members is impracticable." Rule 23(a)(1). "The numerosity requirement requires examination of the specific facts of each case and imposes no absolute limitations." *Gen. Tel. Co. of the Northwest, Inc. v. EEOC*, 446 U.S.

318, 330 (1980). Defendants do not contest the numerosity of the eighty-one member proposed class.

6. ASCERTAINABILITY.

Finally, though not an explicit component of Rule 23, and one to which our court of appeals has not yet definitively spoken, many courts in this circuit have long imposed the requirement that "[a] class definition should be precise, objective, and presently ascertainable." *See Senne v. Kansas City Royals Baseball Corp.*, 315 F.R.D. 523, 542 (N.D. Cal. 2016) (Chief Magistrate Judge Joseph C. Spero); *Xavier v. Philip Morris USA*, 787 F. Supp. 2d 1075, 1089–90 (N.D. Cal. 2011); *O'Connor v. Boeing N.A.*, 184 F.R.D. 311, 319 (C.D. Cal. 1998) (Judge Audrey B. Collins). Among others, the requirement "allow[s] potential class members to identify themselves for purposes of opting out of a class." *Carrera v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013).

Though the proposed class definition turns on objective criteria, dates and purchases, it remains an open class. That is, by seeking to include within the class purchasers between May 2012 "until the effects of the defendants' conduct ceased," the class by definition includes those who have not yet purchased Glumetza from a defendant. Obviously, until such purchase occurs, those purchasers remain unknown. And, until they become known, we cannot notify them of this class and honor their decision to, if they so choose, opt-out. Thus, the class definition must be limited to those to whom we may provide effective notice at this time.

CONCLUSION

For the foregoing reasons, the following class is **CERTIFIED**:

> All persons or entities in the United States and its territories who directly purchased Glumetza or generic Glumetza from a defendant from May 6, 2012 *until the date of this order*.

Shana Scarlett and Lauren Barnes of Hagens Berman Sobol Shapiro LLP, Steve Shadowen of Hilliard & Shadowen LLC, and Joseph Vanek of Sperling & Slater, P.C. have represented the class effectively since their appointment as interim counsel (Dkt. No. 70) and are **CONFIRMED** as co-lead counsel for the class. By **AUGUST 31, 2020 AT NOON**, the parties shall jointly submit a proposal for class notification with a plan to distribute class notice, including by first-class

mail and internet notice. In crafting their joint proposal, the parties shall please keep in mind the guidelines for notice to class members given in the NOTICE AND ORDER RE PUTATIVE CLASS ACTIONS AND FACTORS TO BE EVALUATED FOR ANY PROPOSED CLASS SETTLEMENT (Dkt. No. 39).

IT IS SO ORDERED.

Dated: August 15, 2020.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE

United States District Court
Northern District of California