

EXHIBIT 1

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE: XYREM (SODIUM OXYBATE)
ANTITRUST LITIGATION

Case No. 3:20-md-02966-RS

THIS FILING RELATES TO: ALL CLASS
ACTIONS

**[PROPOSED] FINAL ORDER AND
JUDGMENT APPROVING CLASS
ACTION SETTLEMENT AND
CERTIFYING SETTLEMENT CLASS**

1 On February 28, 2023, Class Representative Plaintiffs¹ entered into a settlement agreement
 2 with Defendants Amneal Pharmaceuticals LLC (“Amneal”) and Lupin Ltd, Lupin Pharmaceuticals
 3 Inc., and Lupin, Inc. (“Lupin,” and, collectively, the “Settling Defendants”).² The Amnea/Lupin
 4 Settlement resolved Class Representative Plaintiffs’ antitrust, consumer protection, and unjust
 5 enrichment claims against the Settling Defendants for allegedly engaging in a course of conduct to
 6 prevent or delay generic competition and maintain a monopoly with respect to brand name
 7 prescription drug Xyrem. On March 3, 2023, Class Representative Plaintiffs moved the Court for
 8 preliminary approval of the proposed class action settlement, the terms and conditions of which are
 9 set forth in the Settlement Agreement filed with the Court. The Court granted preliminary approval
 10 on May 12, 2023 (ECF 500).

11 Class Representative Plaintiffs moved the Court for final approval of the proposed class
 12 action settlement. The Court has read and considered Class Representative Plaintiffs’ Notice of
 13 Motion and Motion for Final Approval of the Class Action Settlement and Certification of the
 14 Settlement Class (“Motion”) and supporting documents, including the Joint Declaration of Co-Lead
 15 Counsel and the Declaration of Eric J. Miller. (ECF 547)

16 For the reasons described more fully below, the Court GRANTS final approval of the
 17 Amneal/Lupin Settlement and certifies the Settlement Class for settlement purposes only.

18 **I. FINDINGS OF FACT AND CONCLUSIONS OF LAW**

19 **A. Notice and Administration**

20 Following entry of the Court’s preliminary approval order, the Class Settlement
 21 Administrator established a settlement website at inrexyremantitrustlitigation.com, which included,

22
 23 ¹ The capitalized terms used in this Order shall have the same meaning as defined in the Class
 24 Settlement Agreement except as otherwise noted.

25 ² The proposed settlement does not include Jazz Pharmaceuticals Plc, Jazz Pharmaceuticals, Inc.,
 26 and Jazz Pharmaceuticals Ireland Limited (collectively, “Jazz”), Hikma Labs, Inc. (formerly known
 27 as Roxane Laboratories, Inc.), Hikma Pharmaceuticals USA Inc. (formerly known as West-Ward
 28 Pharmaceuticals Corp.), Eurohealth (USA), Inc., Hikma Pharmaceuticals plc. (collectively,
 “Hikma”), or Par Pharmaceuticals, Inc. (“Par”). Par remains a Defendant in this action, but
 proceedings as to Par were stayed in August 2022, due to its Notice of Suggestion of Bankruptcy
 Upon the Record. *See* ECF 311. No class or individual claims against the non-settling Defendants
 will be released, and the litigation against those Defendants will continue.

1 among other things: the long-form notice (which explained the procedures for class members to
2 object or exclude themselves), contact information for the Class Settlement Administrator, the
3 Settlement Agreement, and Court documents related to the Form and Manner of Notice. (*See* ECF
4 547). The Settlement Administrator also operated a toll-free number for Settlement Class member
5 inquiries (*Id.*).

6 Notice of the Amneal/Lupin Settlement was provided by: (1) direct notice via USPS First-
7 Class Mail to entities in A.B. Data's TPP Database; (2) direct notice to the consumers identified in
8 the pharmacy dispensing data for Xyrem and via email and, for those whose email was not
9 available, via mail; (3) publication notice, which comprised approximately 12 million impressions
10 and targeted likely settlement class members, on relevant websites and social media platforms; and
11 (4) publication on the settlement website. (*Id.* at 2-3).

12 The Court finds that the Notice Plan provided the best practicable notice to the Settlement
13 Class members and satisfies the requirements of due process.

14 Settlement Class members were given until November 27, 2023, to object or to exclude
15 themselves from the proposed Settlement. Sixteen third party payor class members have opted out
16 and no objections have been filed.

17 **B. Certification of the Settlement Class**

18 For purposes of the Class Settlement only and this Order and Judgment, Class
19 Representative Plaintiffs have moved to certify the following Settlement Class: "All persons and
20 entities in the United States that, for consumption by themselves, their families, their members,
21 employees, insureds, participants, or beneficiaries, and other than for resale, paid and/or provided
22 reimbursement for some or all the purchase price for Xyrem and/or Xywav during the time from
23 January 1, 2015, through the Execution Date." The Execution Date, and thus the end of the
24 settlement class period, is February 28, 2023. Excluded from the Settlement Class are: (1)
25 Defendants and their counsel, officers, directors, management, employees, parents, subsidiaries, and
26 affiliates; (2) Express Scripts Specialty Distribution Services, Inc. and any of its counsel, officers,
27 directors, management, employees, parents, subsidiaries, and affiliates; (3) federal and state
28 governmental entities, not including cities, towns, municipalities, counties or carriers for Federal

1 Employee Health Benefit plans; (4) any “single flat co-pay” consumers whose benefit plan requires
2 a co-payment that does not vary based on the drug’s status as a brand or generic; and (5) all judges
3 assigned to this case and any members of their immediate families.

4 The Court has certified for litigation purposes similar classes asserting antitrust and
5 consumer protection claims against the Remaining Defendants. The Settlement Class is co-
6 extensive with the certified classes, except that the Settlement Class claims have a different end
7 date, have an earlier start date, include purchasers nationwide, and include purchases of Xywav in
8 addition to Xyrem. The an end date based on when the parties settled is appropriate and necessary
9 for administration purposes. *See Foster v. Adams & Assocs.*, 2021 WL 4924849, at *3 (N.D. Cal.
10 Oct. 21, 2021) (granting modification to the previously certified class to specify end date). And the
11 start date is similarly justifiable. The class period in the operative complaint began in 2015, and as
12 such, this date was the date the parties had in mind when they negotiated the settlement. There is
13 also good reason to settle the claims of purchasers nationwide, particularly in light of the certified
14 nationwide injunctive relief class. Including nationwide and Xywav purchases in the settled claims
15 does not change the overall common nature of the claims or the benefits derived from the
16 Settlement, and does not alter the Court’s class certification analysis, except that the predominance
17 analysis operates differently and is more relaxed in the settlement context. *See In re Hyundai & Kia*
18 *Fuel Econ. Litig.*, 926 F.3d 539, 558 (9th Cir. 2019). The Court finds that the Settlement Class
19 largely overlaps with the classes certified by the Court and that, for settlement purposes only, there
20 is a sound basis for the differences in the Settlement Class definition.

21 Accordingly, the Court finds as follows, for purposes of Settlement only:

22 a. Members of the Settlement Class are so numerous as to make joinder impracticable.
23 Express Scripts Specialty Distribution Service, the sole pharmacy which dispenses all Xyrem and
24 Xywav, confirms that tens of thousands of prescriptions for Xyrem and/or Xywav are filled each
25 month. Accordingly, the proposed Settlement Class likely contains hundreds or thousands of
26 members.

27 b. There are questions of law and fact common to the Settlement Class. The litigation
28 will focus on Defendants’ alleged anticompetitive conduct, including whether the Defendants

1 entered into unlawful agreements in restraint of trade to prevent or delay entry of generic
2 competition. *See In re High-Tech Emp. Antitrust Litig.*, 985 F. Supp. 2d 1167, 1180 (N.D. Cal.
3 2013) (“Antitrust liability alone constitutes a common question that ‘will resolve an issue that is
4 central to the validity’ of each class member’s claim ‘in one stroke . . . because proof . . . will focus on
5 defendants’ conduct and not on the conduct of individual class members.’”) (citing *Wal-Mart Stores,*
6 *Inc. v. Dukes*, 564 U.S. 338, 350 (2011)).

7 c. Th common questions of law and fact predominate over any questions affecting only
8 individual Settlement Class members for purposes of the Settlement because the Defendants’
9 conduct—*i.e.* whether it was illegal and what impact it had on the prices paid by class members—
10 will drive the litigation. That is particularly true in the settlement context. As the Ninth Circuit has
11 held, “predominance is easier to satisfy in the settlement context.” *Jabbari v. Farmer*, 965 F.3d
12 1001, 1006 (9th Cir. 2020); *see also Sullivan v. DB Inv., Inc.*, 667 F.3d 273, 304 n. 29 (3d Cir.
13 2011) (*en banc*) (courts are “more inclined to find the predominance test met in the settlement
14 context”) (internal quotation marks and alteration omitted). That is because “[s]ettlement may
15 ‘obviate the need to litigate individual issues that would make a trial unmanageable,’ making
16 common questions more important in the relative analysis.” *Jabbari*, 965 F.3d at 1005-06
17 (quoting *Hyundai*, 926 F.3d at 558). While the Court in its certification order excluded Xywav
18 from the litigation classes (*see* ECF 500 at 16), this does not preclude certification of the Settlement
19 Class as the settlement obviates the need to determine which Xywav patients would or could have
20 been prescribed Xyrem instead. *See In re ZF-TRW Airbag Control Units Prod. Liab. Litig.*, 2023
21 WL 6194109, at *12 (C.D. Cal. July 31, 2023) (“A class may be certifiable for settlement even
22 though it may not be certifiable for litigation where the settlement obviates the need to litigate
23 individualized issues that would make a trial unmanageable.”) (internal quotations and citations
24 omitted).

25 d. Class Representative Plaintiffs’ claims are typical of the claims of the Settlement
26 Class members for purposes of the Settlement. Class Representative Plaintiffs’ injuries
27 (supracompetitive prices) stem from the same course of conduct (Defendants’ anticompetitive
28

1 conduct) and seek to recover pursuant to the same legal theories (unlawful restraint of trade and
2 monopolization).

3 e. Class Representative Plaintiffs and their counsel have fairly and adequately protected
4 the interests of the Settlement Class members in this action, and will continue to do so. Each
5 plaintiff has the same goal as members of the Settlement Class (*i.e.*, proving the Defendants acted
6 unlawfully and that they paid, and continue to pay, overcharges as a result). Class Representative
7 Plaintiffs' interests are aligned with, and not in conflict with, those of Settlement Class members.
8 The record reflects that each Class Representative Plaintiff has dedicated substantial time and effort
9 to this litigation by working with their counsel; reviewing pleadings; responding to discovery;
10 searching for, collecting, and producing documents; and preparing to sit for depositions, among
11 other things.

12 f. A class action is superior to all other available methods for fairly and efficiently
13 resolving this action. A class action avoids congesting the Court with the need to repeatedly
14 adjudicate such actions; prevents the possibility of inconsistent results; and allows class members an
15 opportunity for redress that might otherwise be denied.

16 The Court further finds, for the reasons stated in the Motion, that Class Representative
17 Plaintiffs and co-Lead class counsel should be appointed to represent the Settlement Class. The
18 Court appoints Dena C. Sharp of Girard Sharp LLP and Michael M. Buchman of Motley Rice LLC
19 as co-lead class counsel for the Settlement Class.

20 **C. Final Approval of Settlement**

21 A court may approve a proposed class action settlement only “after a hearing and on finding
22 that it is fair, reasonable, and adequate after considering whether:

23 (A) the class representatives and class counsel have adequately represented the
24 class; (B) the proposal was negotiated at arm’s length; (C) the relief provided for
25 the class is adequate, taking into account: (i) the costs, risks, and delay of trial and
26 appeal; (ii) the effectiveness of any proposed method of distributing relief to the
27 class, including the method of processing class-member claims; (iii) the terms of
28 any proposed award of attorney's fees, including timing of payment; and (iv) any
agreement required to be identified under Rule 23(e)(3); and (D) the proposal treats
class members equitably relative to each other.

1 Fed. R. Civ. P. 23(e)(2).³ In reviewing the proposed settlement, the Court need not address whether
2 the settlement is ideal or the best outcome, but only whether the settlement is fair, free of collusion,
3 and consistent with plaintiff’s fiduciary obligations to the class. *See Hanlon v. Chrysler Corp.*, 150
4 F.3d 1011, 1027 (9th Cir. 1998).

5 For the reasons detailed below, the Court finds that the proposed settlement is fair,
6 reasonable, and adequate under the Rule 23(e)(2) factors. Continued litigation against the Settling
7 Defendants involves substantial risks and would complicate the litigation against the Remaining
8 Defendants. Defendants dispute Class Representative Plaintiffs’ theories of anticompetitive harm
9 and causation. There would also have been a battle of the experts regarding, among other things,
10 whether the Settling Defendants’ agreements with Jazz were anticompetitive; the anticompetitive
11 effects of Settling Defendants’ conduct; and what damages, if any, should be awarded. Proceeding to
12 trial as against the Settling Defendants would have been costly, recovery was not guaranteed, and
13 there was the possibility of protracted appeals. The Amneal/Lupin Settlement avoids these risks
14 while providing substantial benefits to the Settlement Class, was the product of arms-length
15 negotiations among experienced counsel, and there is no factual basis to support any allegation of
16 collusion or self-dealing.

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21 ³ Prior to the amendments to Rule 23, which took effect December 1, 2018, the Ninth Circuit had
22 enumerated a similar list of factors to consider in evaluating a proposed class settlement. *See*
23 *Churchill Vill., L.L.C. v. Gen. Elec.*, 361 F.3d 566, 575 (9th Cir. 2004) (enumerating the following
24 factors: “(1) the strength of the plaintiffs’ case; (2) the risk, expense, complexity, and likely duration
25 of further litigation; (3) the risk of maintaining class action status throughout the trial; (4) the amount
26 offered in settlement; (5) the extent of discovery completed and the stage of the proceedings; (6) the
27 experience and views of counsel; (7) the presence of a governmental participant; and (8) the reaction
28 of the class members to the proposed settlement”). In the notes accompanying the Rule 23
amendments, the Advisory Committee explained that the amendments were not designed “to
displace any factor, but rather to focus the court and the lawyers on the core concerns of procedure
and substance that should guide the decision whether to approve the proposal.” Accordingly, this
Court applies the framework of Rule 23 while “continuing to draw guidance from the Ninth Circuit’s
factors and relevant precedent.” *Hefler v. Wells Fargo & Co.*, 2018 WL 6619983, at *4 (N.D. Cal.
Dec. 17, 2018), *aff’d sub nom. Hefler v. Pekoc*, 802 F. App’x 285 (9th Cir. 2020).

1 **1. Class Representative Plaintiffs and Class Counsel Have Adequately**
 2 **Represented the Settlement Class**

3 In the Preliminary Approval Order, the Court found that the Class Representative Plaintiffs,
 4 as well as co-lead class counsel and members of the Plaintiffs’ Steering Committee (“Class
 5 Counsel”), adequately represented the interests of the certified classes. The Court has seen no
 6 evidence to contradict its previous finding, and the Court reconfirms it here with respect to Class
 7 Representative Plaintiffs and Class Counsel, who have vigorously prosecuted this action through
 8 discovery, motion practice, mediation, and preparations for trial. Class Counsel “possessed sufficient
 9 information to make an informed decision about settlement.” *Hefler*, 2018 WL 6619983, at *6.

10 **2. The Class Settlement Was Negotiated at Arm’s Length**

11 The Amneal/Lupin Settlement is the product of serious, non-collusive, arm’s length
 12 negotiations by experienced counsel. Prior to reaching a settlement, the parties engaged in extensive
 13 fact discovery. The record was thus sufficiently developed to full inform the parties and enable them
 14 to evaluate the strengths and weaknesses of their respective positions. *See Nat’l Rural Telecomm.*
 15 *Coop. v. DIRECTV*, 221 F.R.D. 523, 528 (C.D. Cal. 2004); 4 A. Conte & H. Newberg on Class
 16 Actions at § 11.24 (4th ed. 2002) (“A court is more likely to approve a settlement if most of the
 17 discovery is completed because it suggests that the parties arrived at a compromise based on a full
 18 understanding of the legal and factual issues surrounding the case.”).

19 The Court has independently and carefully reviewed the record for any signs of collusion and
 20 self-dealing and finds no such signs. The Court finds that Class Counsel did not compromise the
 21 claims of the Settlement Class in exchange for higher fees as there has been no agreement
 22 concerning attorneys’ fees or otherwise disadvantaging the Settlement Class.

23 **3. The Settlement Provides Adequate Recovery to the Class**

24 In the Rule 23(e) analysis, “[t]he relief that the settlement is expected to provide to class
 25 members is a central concern.” Fed. R. Civ. P. 23(e)(2)(C)-(D) advisory committee’s note to 2018
 26 amendment. “The Court therefore examines ‘the amount offered in settlement.’” *Hefler*, 2018 WL
 27 6619983 *8 (quoting *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1026 (9th Cir. 1998)).

28 The Settling Defendants have agreed to pay \$3.4 million, which will be used to pay costs and
 expenses incurred in the ongoing litigation against the Remaining Defendants. The terms provide

1 substantial benefit to Settlement Class members, as the proceeds of the Settlement will be used to
2 advance the pursuit of recoveries from the Remaining Defendants. The Amneal/Lupin Settlement
3 does not encumber other, separate claims that class members might have, nor does it prevent the
4 Settlement Class from seeking the full measure of the anticompetitive overcharge damages that may
5 be recovered from Jazz and Hikma. The Court finds that this recovery is fair, reasonable, and
6 adequate given the risks of proceeding to trial against the Settling Defendants and the continued
7 availability of recoveries from the Remaining Defendants.

8 **4. The Risk of Continued Litigation**

9 The amount provided for in the Amneal/Lupin Settlement is also reasonable in light of the
10 risks of continued litigation. There are substantial disputes as to whether Class Representative
11 Plaintiffs will be able to prove at trial that Amneal and Lupin's conduct, as later-filing generics,
12 caused the anticompetitive overcharges that the Class has paid. Both sides believed they had
13 persuasive facts to support their positions. Defendants would have attacked Class Representative
14 Plaintiffs' theories of anticompetitive harm and causation at summary judgment. Trial would have
15 involved a clash of expert analysis as to: whether the Settling Defendants' agreements with Jazz
16 were anticompetitive; the anticompetitive effects of Settling Defendants' conduct; and what
17 damages, if any, should be awarded. Success at trial was far from guaranteed. Amneal and Lupin
18 were prepared to assert procompetitive justifications and causation and injury affirmative defenses.
19 And even if Class Representative Plaintiffs succeeded at trial, appeals would undoubtedly have
20 followed.

21 **5. Attorneys' Fees and Expenses**

22 The parties have reached no agreement regarding the amounts of attorneys' fees, expenses,
23 and service wards to be paid. *See, e.g., Hyundai.*, 926 F.3d at 569-70 (rejecting fairness objection
24 because class counsel "did not reach an agreement with the automakers regarding the amount of
25 attorney's fees to which they were entitled," which "[p]rovid[es] further assurance that the
26 agreement was not the product of collusion"). Class Representative Plaintiffs and Class Counsel
27 have not sought the payment of any attorneys' fees or the reimbursement of any accrued expenses
28 from the Settlement Fund. This factor thus weighs in favor of approval.

1 **6. Other Agreements**

2 The Court is required to consider “any agreements required to be identified under Rule
3 23(e)(3).” The Court has reviewed the Settlement Agreement and relevant accompanying materials.
4 The Court is also aware that the Amneal/Lupin Settlement provides for the creation of a escrow
5 account to hold assets on behalf of the Settlement Class and for use in the continued litigation
6 against the Remaining Defendants for the benefit of the Settlement Class. The Court find that such
7 an agreement is appropriate.

8 **7. The Settlement is Reasonable and Treats Class Members Equitably**

9 The Settlement Fund of \$3,400,000 and any accrued interest or earnings after deposit will be
10 held in escrow and used to pay litigation costs and expenses incurred in Class Representative
11 Plaintiffs’ continued litigation against the remaining Defendants. The relief thus treats class
12 members equitably relative to each other because the class will benefit from the continued litigation
13 against the Remaining Defendants.

14 **8. The Response of Class Members**

15 Out of the thousands of notices delivered and the millions of impressions from banner and
16 social media ads, sixteen opt-outs and no objections have been received. ECF 547 at 4. These figures
17 represent a very positive response from the class. *See Churchill*, 361 F.3d at 577 (noting a court may
18 infer appropriately that a class action settlement is fair, adequate, and reasonable when few class
19 members object to it); *Zepeda v. PayPal, Inc.*, 2017 WL 1113293, at *16 (N.D. Cal. Mar. 24, 2017)
20 (“[T]he indisputably low number of objections and opt-outs, standing alone, presents a sufficient
21 basis upon which a court may conclude that the reaction to settlement by the class has been
22 favorable); *Cruz v. Sky Chefs, Inc.*, 2014 WL 7247065, at *5 (N.D. Cal. Dec. 19, 2014) (“A court
23 may appropriately infer that a class action settlement is fair, adequate, and reasonable when few
24 class members object to it.”). Accordingly, the response of the Settlement Class weighs in favor of
25 approval.

26 **D. Releases and Effect of This Order**

27 By operation of this Order and Judgment, once the Settlement becomes Final as set forth in
28 the Settlement Agreement, Settlement Class members, including the Class Representative Plaintiffs,

1 release and forever discharge and hold harmless the Settling Defendants and the Released Parties of
2 any and all Released Claims. The claims of Class Representative Plaintiffs against the Settling
3 Defendants are hereby dismissed with prejudice.

4 **E. Costs of Administering the Settlement**

5 The Settlement Administrator has submitted \$195,926.52 in invoices to-date and projects that
6 it will incur approximately \$5,000 in additional billing to complete the notice program and related
7 activities. Given the uncertainty in the final amounts needed to complete settlement administration,
8 the Court authorizes payment to the Settlement Administrator of *up to* \$203,000.00. Class Counsel
9 shall, however, only authorize payments to the Settlement Administrator for actual costs incurred.
10 Any difference between the actual costs incurred by the Settlement Administrator and the
11 \$203,000.00 approved amount shall remain a part of the Settlement Fund.

12 **F. Other Effects of This Order**

13 No action taken by the parties, either previously or in connection with the negotiations or
14 proceedings connected with the Settlement, shall be deemed or construed to be an admission of the
15 truth or falsity of any claims or defenses heretofore made or an acknowledgment or admission by
16 any party of any fault, liability or wrongdoing of any kind whatsoever to any other party. Neither
17 the Settlement nor any act performed or document executed pursuant to or in furtherance of the
18 Settlement: (a) is or may be deemed to be or may be used as an admission of, or evidence of, the
19 validity of any claim made by the Settlement Class members or Class Counsel, or of any
20 wrongdoing or liability of the persons or entities released under this Order and Judgment and the
21 Settlement, or (b) is or may be deemed to be, or may be used as an admission of, or evidence of, any
22 fault or omission of any of the persons or entities released under this Order and Judgment and the
23 Settlement, in any proceeding in any court, administrative agency, or other tribunal.

24 This Order and Judgment shall constitute a final judgment under Federal Rule of Civil
25 Procedure 54(b) binding the Released Parties and Settlement Class members with respect to the
26 Released Claims.

27 No payments shall be made from the Settlement Fund, or from any account holding the
28 Settlement Fund, without the written authorization of Class Counsel.

1 No Settlement Class member or any other person may sue or have any claim or cause of
2 action against the Class Representative Plaintiffs, Class Counsel or any person designated by Class
3 Counsel, or the Settlement Administrator arising from or relating to the Settlement, the Released
4 Claims, or the litigation.

5 Without affecting the finality of the Judgment hereby entered, the Court reserves exclusive
6 jurisdiction over the implementation of the Settlement.

7 There is no just reason for delay in the entry of this Order and Judgment, and immediate
8 entry by the Clerk of the Court is expressly directed.

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10 Dated: _____, 2024

11 _____
12 Hon. Richard Seeborg
13 Chief U.S. District Court Judge
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