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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

VALUE DRUG COMPANY, on behalf of itself and all others similarly situated,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS, INC.; IMPAX LABORATORIES, INC.; ZYDUS PHARMACEUTICALS (USA) INC.; and ZYDUS LIFESCIENCES LIMITED,

Defendants.

Case No. 3:26-cv-7780

CLASS ACTION COMPLAINT

Jury Trial Demanded

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Plaintiff Value Drug Company ("Plaintiff"), on behalf of itself and all others similarly situated, brings this Class Action Complaint against Impax Laboratories, Inc. and its parent Amneal Pharmaceuticals, Inc. (collectively, "Impax"); and Zydus Pharmaceuticals (USA) Inc. and its parent Zydus Lifesciences Limited (f/k/a Cadila Healthcare Ltd.) (collectively, "Zydus") (together Impax and Zydus are "Defendants"), and alleges as follows based on: (a) personal knowledge, (b) the investigation of its counsel, and (c) information and belief:

I. Introduction

1. This is an antitrust class action arising from an anticompetitive market allocation scheme between pharmaceutical manufacturer Impax, and generic manufacturers Actavis Laboratories FL, Inc., Actavis Pharma Inc. (collectively, "Actavis"), and Zydus, to suppress price competition for Impax's brand drug Rytary, a combination of carbidopa (an aromatic amino acid decarboxylation inhibitor) and levodopa (an aromatic amino acid) indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.

2. Defendant Impax holds the Rytary new drug application ("NDA") and the associated patents Impax listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), an FDA publication listing patents that claim an approved drug or its approved method of use. Impax has earned hundreds of millions of dollars in annual Rytary sales in the United States in recent years. Actavis and Zydus are two of many generic drug manufacturers that sought to compete with Impax by launching a generic version of Rytary.

3. Rather than compete as independent market participants, Actavis and then Zydus agreed that they would abandon their efforts to break open the Rytary generic market to competition, which would have resulted in a dramatic shift of sales from the high-priced brand product to the lower-priced generics. In exchange, Impax agreed to give Actavis and Zydus inducements that they could not win through the patent litigation, as detailed below.

4. Because generics, once they enter a market, typically take nearly all the brand's market share, brands typically launch an AG once generic competition starts to compete with the generics and

recapture some of those lost sales. Here though, Impax would license Actavis as the sole seller of generic Rytary for the first 80 days of generic competition, starting on July 31, 2025. During those 80 days, Impax agreed that it would not launch an "authorized generic" or "AG," which is a version of the brand product in generic trade dress. This "No-AG" deal was a significant inducement that Actavis could never have obtained from a patent litigation victory, and it was a large and unjustified reverse payment.

5. A couple of years later, Impax made a parallel arrangement with Zydus. In exchange for Zydus's abandoning its efforts to break open the market in patent litigation, Impax agreed to license Zydus as a selling partner for AG Rytary. That license would not begin until October 20, 2025, over 5 years after the May 2020 Impax-Zydus settlement, and 81 days after Actavis's licensed entry date. The Impax-Zydus agreement would illegally protect both Zydus and Actavis from full competition from other generic manufacturers because Impax agreed not to compete with Zydus's AG with a second generic.

6. This scheme and the unlawful market allocations allowed Impax to continue to charge supracompetitive prices and enjoy monopoly profits on its Rytary sales that would have otherwise precipitously declined had generic entry occurred earlier. As a result, Rytary purchasers have paid hundreds of millions of dollars in overcharges on both brand and generic purchases from Defendants Impax and Zydus.

7. Congress enacted the Hatch-Waxman Act to accelerate entry of lower-cost generic drugs. The Act incentivizes generic competition by awarding the "first-to-file" or "FTF" generic manufacturer that submits a substantially complete Abbreviated New Drug Application ("ANDA") challenging the brand's listed patents, a 180-day marketing exclusivity period. During that 180-day window, the FDA cannot approve another generic ANDA product to compete with the FTF. This exclusivity is both valuable and exploitable: if the FTF applicant's launch is delayed, either because it was induced by the brand to delay or because the FDA has shifted approval standards in the middle of its review of the FTF's application, every subsequent generic filer is bottlenecked behind the FTF for the full duration of the exclusivity period following its launch.

8. Under certain limited conditions, the FTF's 180-day exclusivity can be forfeited. As relevant here, the 180-day exclusivity could be forfeited when the FTF (a) fails to market the product within 75 days after a judgment from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the listed patent(s) is (are) invalid, unenforceable, or not infringed (the "Failure to Market" forfeiture provision); or (b) fails to obtain tentative approval[1] of its ANDA within 30 months of the date the ANDA was accepted for filing by FDA, unless the failure is caused by a change in, or a review of, the requirements for approval of the application imposed after the date on which the application is filed (the "Failure to Obtain Timely Approval" forfeiture provision).

9. In June 2015, Actavis filed the first Rytary ANDA (ANDA No. 208522), earning the FTF position and eligibility for its associated 180-day exclusivity.

10. During the FDA approval process, the FDA determined that Actavis did not forfeit under the Failure to Obtain Timely Approval forfeiture provision, so that forfeiture provision was not a threat to Actavis's 180-day exclusivity, despite Actavis not getting FDA approval within 30 months of ANDA filing. But, as set forth below, the separate Failure to Market forfeiture provision threatened forfeiture of Actavis's 180-day exclusivity, and that forfeiture would have resulted in the launch of generic Rytary *years* before such launch actually occurred.

11. Shortly after Actavis filed its ANDA, Impax filed a Hatch-Waxman patent suit against Actavis in September 2015, triggering the 30-month Hatch-Waxman stay of FDA approval. After the parties litigated through trial, they settled in June 2018, before the court issued a decision, with Actavis accepting a launch date of July 31, 2025, more than seven years away. But the long delay to Actavis's launch was not a reflection of the strength of Impax's Rytary patents. Indeed, the patents were extraordinarily weak.

12. Rather, Impax and Actavis knew that an Actavis trial victory would usher in generic competition. Impax did not want to lose its lucrative Rytary monopoly, so it agreed that if Actavis

[1] Tentative approval means the FDA has determined that the ANDA meets all applicable safety, efficacy, and labeling requirements and could otherwise earn final approval, but that final approval cannot be granted at that time due to an existing patent or regulatory exclusivity, or a 30-month stay associated with Paragraph IV Hatch-Waxman litigation.

delayed its generic entry until July 31, 2025, Impax would not launch an AG to compete with Actavis's generic for 80 days, until October 20, 2025, even though such agreement was against Impax's unilateral economic interests. There was no public announcement of this 80-day No-AG term.

13. Absent the Impax-Actavis reverse payment (Impax's agreement to not launch an AG for 80 days), Actavis would have prevailed in the patent litigation, and would have paved the way for multiple ANDA filers to launch years earlier than competition actually occurred.

14. The Impax-Actavis agreement also had the effect of blocking multiple other ANDA filers from competing, by bottlenecking their approval behind Actavis's now-delayed 180-day exclusivity.

15. The only way for those ANDA filers to circumvent Actavis's 180-day exclusivity would be to obtain entry of a court judgment against Impax as to every single patent that qualified Actavis for its 180-day exclusivity (*i.e.*, the patents Impax listed in the Orange Book at the time Actavis filed its ANDA).

16. In fact, Actavis never obtained FDA approval, and it did not launch on July 31, 2025, or at any time thereafter. The bottleneck has prevented multiple Rytary ANDA filers from obtaining approval from the FDA. For example, Sandoz Inc. ("Sandoz") filed a Rytary ANDA (ANDA No. 208895) in December 2016 and settled with Impax in December 2018; it received tentative approval in March 2023, meaning that the FDA would have approved its generic Rytary ANDA by that time (or earlier) but for Actavis's FTF 180-day exclusivity. But Sandoz could not receive, and has not received final FDA approval because of the bottleneck – the 180-day exclusivity still has not been triggered. If no bottleneck had been in place, Sandoz would have pressed for, and FDA would have conducted, a more timely review, and Sandoz would have received approval for its ANDA and launched much earlier and certainly no later than March 2023.

17. Zydus also has not launched a generic approved under its own ANDA, but that is because of its own anticompetitive arrangement with Impax. As stated above, a subsequent ANDA filer, like Zydus, can trigger the forfeiture of the FTF's (Actavis's) 180-day exclusivity by securing a judgment as to each patent qualifying the FTF for 180-day exclusivity. To that end, Zydus filed its Rytary ANDA (ANDA No. 210911) in August 2017 and mounted an aggressive patent challenge. On April 27, 2018,

after Impax filed suit asserting infringement of U.S. Patent No. 9,089,608 (the "'608 patent"), Zydus asserted declaratory judgment counterclaims as to the '608 patent as well as all the other Impax patents that had qualified Actavis for 180-day exclusivity. In November 2018, Judge Stanley Chesler of the District of New Jersey granted Zydus's Rule 12(c) motion, awarding Zydus judgment of noninfringement on five of the six counterclaim patents. Following this ruling, the '608 patent was the only patent preserving the Rytary generic approval bottleneck, and it was proceeding to trial. By early 2020, Zydus was poised to win that lone remaining patent dispute outright.

18. Zydus understood precisely what a trial victory would mean. In its own counterclaims, Zydus explained that a final judicial decision of invalidity or noninfringement in its favor on the patents qualifying Actavis for 180-day exclusivity "could affect when the first filer must market its product or otherwise forfeit any 180-day marketing exclusivity." A Zydus win at trial in 2020 and appeal (if taken) would have started the forfeiture clock: if Actavis then failed to market within 75 days, Impax's carefully orchestrated bottleneck, secured by the reverse payment it agreed to provide Actavis, would collapse, opening Rytary to competition from Zydus's independent ANDA product and from Sandoz and others as well.

19. Impax could not allow that to happen, so it paid Zydus to stand down. With trial pending in 2020 as to the '608 patent, Impax and Zydus jointly moved to dismiss the litigation. Impax and Zydus kept their arrangement secret. There was no contemporaneous public announcement of any settlement containing the terms challenged herein. In this arrangement, Zydus agreed to quit the patent fight and thus not disturb the Actavis bottleneck blocking all generic approvals. In exchange, Zydus could launch the AG, the brand's product in a different trade dress, in October 2025, and Impax agreed not to compete with its own generic.

20. By licensing Zydus to launch the AG that Impax would have otherwise launched in competition with Zydus's ANDA product, this arrangement guaranteed one fewer generic on the market, and guaranteed that prices would be wrongfully elevated at the expense of purchasers. Further, as long as the Actavis bottleneck remained in place, the Impax-Zydus agreement ensured that Zydus would not

face any additional generic competition from the time of its AG launch in October 2025 through December 2028, when the patents purportedly covering Rytary expire.

21. Impax's plan worked. Because Actavis never launched its ANDA product, all ANDAs remain bottlenecked behind Actavis's FTF 180-day exclusivity. Zydus restricted its own output by delaying entry of its ANDA product and agreed to a market division with Impax of the incumbent monopoly product by launching the Rytary AG, which is just the brand product with different labeling, in October 2025. In exchange, Impax agreed not to, and has not, competed with Zydus by launching a competing generic as it would have if it were pursuing its unilateral economic interests. There remains only one generic on the market – the Zydus AG. The lack of generic competition allows Zydus to charge higher prices for generic Rytary than it would in a market with multiple generics competing on price. Absent this unlawful arrangement, Zydus would have broken the Actavis bottleneck and launched earlier with its ANDA product, Impax would have launched a competing generic, either by itself or through another distributor, and other ANDA filers would have launched as well.

22. The Impax-Zydus agreement transformed the Defendants' economic incentives completely. Typically, brand companies will not launch an AG before the FTF launches a generic, waiting instead for an ANDA generic to launch, because the launch of a generic (whether via an ANDA or an AG) results in sales shifting away from the higher-priced brand to the lower-priced generic, thereby eviscerating the high revenue brand sales. However, once a generic launches, marketing a competing AG makes economic sense for the brand company because the AG allows the brand company to capture a share of generic sales (*i.e.*, participate in the generic part of the market). Here, in contrast, Impax allowed a would-be ANDA generic competitor, Zydus, to launch as an AG first, in the absence of other generic competition, and did not compete with Zydus with a generic once Zydus entered. These acts were against Impax's non-conspiratorial, unilateral economic self-interests and not unilaterally rational, profit-maximizing behavior. Impax's conduct was rational, however, in its conspiratorial interests: Impax was willing to cede a slice of the market to Zydus as long as Zydus agreed to not break the Actavis bottleneck and to delay its ANDA launch, thereby allowing Impax to illegally maintain its Rytary monopoly (and profits) for several years longer than it otherwise would have based on its

extraordinarily weak patents. In exchange, Zydus enjoyed less generic competition (and therefore charged higher generic prices) than it could have if it won the patent litigation.

23. Before the agreement, Zydus had every incentive to litigate and win so that it could launch and start earning money selling generic Rytary as early as possible. But after the agreement, Zydus had every incentive to preserve the bottleneck: so long as Sandoz and other challengers remained bottlenecked, Zydus's authorized generic faced no competition from a bottlenecked ANDA, another AG, or even Actavis's own ANDA product, if Actavis's ANDA did not obtain FDA approval. This artificial limitation to competition, secured via the collusive Impax-Zydus agreement, is not something Zydus could have obtained by prevailing in litigation. As of this complaint, Zydus continues to benefit from the Actavis bottleneck it conspired to help maintain, as it sells the only Rytary generic product on the market and, with the Actavis bottleneck firmly in place, will continue to do so until the Rytary patents expire in December 2028.

24. As a result of Defendants' anticompetitive conduct, Plaintiff and Class Members have been forced to, and continue to, pay hundreds of millions of dollars in brand and/or generic Rytary overcharges on their purchases from Defendants that Plaintiff and Class Members would not have otherwise paid absent the unlawful scheme.

25. Impax's bottlenecking scheme violates Section 2 of the Sherman Act, 15 U.S.C. § 2 by improperly maintaining and extending Impax's monopoly over Rytary. Defendants' joint conduct violates Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2. Plaintiff and Class Members seek treble damages and all other relief available under federal antitrust laws.

II. Parties

26. Plaintiff Value Drug Company is a corporation organized under the laws of Pennsylvania and maintaining its principal place of business at 195 Theater Drive, Duncansville, Pennsylvania 16635. Plaintiff purchased branded Rytary directly from Impax and authorized generic Rytary directly from Zydus during the Class Period as defined below and was injured by the illegal conduct described herein.

27. Defendant Impax Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware and is wholly owned by Defendant Amneal Pharmaceuticals Inc. Impax's

registered business address is 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. At the time of the Impax-Zydus agreement that is the subject of this complaint, Impax had a principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544.

28. Defendant Amneal Pharmaceuticals, Inc. is a corporation organized under the laws of Delaware with a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. On May 7, 2018, Amneal acquired Impax. Impax is now a wholly owned subsidiary of Amneal.

29. At all times following Amneal's acquisition of Impax, Amneal participated in the negotiation and execution of the Impax-Actavis and Impax-Zydus agreements and directed and participated in the anticompetitive conduct alleged in this complaint.

30. Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 N., Pennington, New Jersey 08534.

31. Defendant Zydus Lifesciences Limited, f/k/a Cadila Healthcare Ltd. (d/b/a Zydus Cadila) ("Cadila") is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382 481, India.

32. Zydus and Cadila operate as a single economic unit with respect to ANDA products.

33. Zydus is a wholly owned subsidiary of Cadila.

34. The acts of Zydus complained of herein were done with the cooperation, participation, and assistance of Cadila.

35. Zydus is Cadila's United States domestic agent under 21 C.F.R. § 207.69 with respect to Cadila's marketing of drug products in the United States.

36. Zydus and Cadila are typically joint signatories and participants in Hatch-Waxman settlements and licensees of brand companies. For example, in Hatch-Waxman settlements and licenses

concerning the drugs ribavirin, topiramate, mesalamine, gabapentin and lenalidomide, Zydus and Cadila were collectively defined as Licensee and/or were both parties to the agreement.[2]

37. Each Defendant is in the business of, among other things, developing, preparing, manufacturing, selling, marketing and distributing pharmaceutical products throughout the United States, including the State of California.

III. Jurisdiction and Venue

38. The Court has subject matter jurisdiction over this matter under 28 U.S.C. §§ 1331, 1337(a) and 15 U.S.C. § 15.

39. This action arises under Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1 & 2), violations of which are made privately actionable through Section 4 of the Clayton Act (15 U.S.C. §15(a)), and seeks threefold damages, costs of suit, and reasonable attorneys' fees for the overcharges paid by Plaintiff and members of the proposed class resulting from the conduct alleged herein.

40. Defendants transact business within this district and carry out interstate trade and commerce in substantial part in this district and/or have agents and/or can be found in this district. Venue is therefore appropriate within this district under Section 12 of the Clayton Act (15 U.S.C. § 22) and 28 U.S.C. § 1391(b) and (c).

41. The Court has personal jurisdiction over each Defendant. Defendants have transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

[2] *See* https://www.sec.gov/Archives/edgar/data/1557142/000104746916013747/a2228779zex-10_27.htm (ribavirin); https://www.sec.gov/Archives/edgar/data/1356576/000110465917031191/a17-10293_1ex10d1.htm (topiramate); https://www.zyduslife.com/public/pdf/pressrelease/PressNote11-12-13.pdf (mesalamine); https://www.zyduslife.com/public/pdf/pressrelease/PressNote15-04-14.pdf (gabapentin); https://zyduslife.com/public/pdf/pressrelease/Zydus_Announces_Settlement_of_Patent_Litigation_for_Generic_Revlimid_in_US.pdf (lenalidomide).

IV. DIVISIONAL ASSIGNMENT

42. Assignment is proper to the San Francisco or Oakland Division of this District under Local Rule 3-2(c)-(e) because a substantial portion of the events giving rise to Plaintiff's claims occurred in Hayward, California (Alameda County). Specifically, on information and belief, Defendant Impax devised and negotiated substantial portions of the unlawful scheme described herein from its then-Corporate Headquarters in Hayward, CA, including the Impax-Actavis reverse payment agreement.

V. REGULATORY BACKGROUND

A. Brand Manufacturer NDAs and the FDA's Orange Book

43. Under the Food, Drug, and Cosmetic Act ("FDCA"), drug companies looking to sell a new drug product in the United States must file an NDA with the FDA. An NDA submission must include specific data concerning the safety and effectiveness of the drug.

44. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. Law No. 98-417, 98 Stat. 1585 (1984), an NDA applicant must submit to the FDA information on each patent that claims "the drug" or "a method of using such drug" described in the NDA and for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(viii)(I)-(II). The FDA then publishes this information in a digest titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

45. Once a brand manufacturer lists a patent in the Orange Book, that listing puts potential generic competitors on notice that the brand considers the patent to cover its drug substance, formulation, or method of use. "[T]he FDA does not verify that submitted patents actually meet the statutory listing criteria, nor does the FDA proactively remove improperly listed patents" from the Orange Book. *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC.*, 60 F.4th 1373, 1378 (Fed. Cir. 2023). Rather, the FDA's role with respect to Orange Book patent listings is "purely ministerial." *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003) (noting FDA arguments that (i) FDA does not have a duty to determine "whether the patent claims the drug," (ii) "FDA has only a ministerial role in the listing process," and (iii) "it is the responsibility of the NDA holder to determine whether a patent claims

the drug or a method of using the drug that is the subject of the NDA for purposes of Orange Book listing"). The listing of a patent in the Orange Book triggers various regulatory consequences described below as pertinent here.

B. Generic ANDAs and the Hatch-Waxman Act

46. Congress passed the Hatch-Waxman Act to balance the need to provide brand companies with incentives to develop new medicines against the countervailing need to speed the entry of less expensive generic versions of those medications.

47. The Hatch-Waxman Act enables a generic manufacturer to file an ANDA with the FDA for a generic drug it seeks to bring to market as a less expensive substitute for its corresponding reference listed drug ("RLD"), often referred to as the brand drug. Rather than requiring generic manufacturers to conduct expensive clinical trials to re-prove the drug's safety and efficacy, the Hatch-Waxman Act allows generic manufacturers to rely on the data that brand drug companies already have submitted for the RLD. A generic manufacturer need show only that its generic formulation is pharmaceutically equivalent and bioequivalent to the brand drug. The premise, codified by Congress and implemented by the FDA for the past forty years, is that two drug products that contain the same active pharmaceutical ingredient ("API") in the same dose and route of administration that are absorbed by the human body at the same rate are equally safe and effective.

48. In practical terms, this means that an ANDA applicant must show that the generic drug product described in the ANDA is substantially "the same as" the brand drug. That is, that the generic product contains the same API, route of administration, dosage form, strength, rate and extent of absorption (bioequivalence), at least one of the same conditions of use, and, with certain permissible differences, substantially the same labeling as the brand RLD. Having done so, the ANDA applicant may rely on the FDA's previous finding that the brand drug product is safe and effective because, as a matter of science and decades of experience, there is no reason to believe that the generic product would behave any differently in the body. When a generic application meets those criteria, the FDA assigns the generic drug an "AB" rating. An AB-rated generic is deemed equally as safe and effective as its RLD

and therefore can, and in some states must, be freely substituted for the brand by pharmacies when filling prescriptions.

49. The Hatch-Waxman Act also provides the framework through which a generic manufacturer must address each patent the NDA holder has listed in the Orange Book as claiming its brand drug. To obtain FDA approval of its ANDA, with respect to each Orange Book-listed patent, a generic manufacturer must, with limited exceptions not relevant here, make one of the four certifications enumerated below:

> (I) that such patent information has not been filed (a "Paragraph I certification");
>
> (II) that such patent has expired (a "Paragraph II certification");
>
> (III) that the generic applicant does not seek to market its generic version of the reference-listed drug until the date on which such patent will expire (a "Paragraph III certification"); or
>
> (IV) that the generic applicant seeks to market its generic version of the RLD before the expiration date of the patent, but that such patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the generic drug for which the application is submitted (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

C. Paragraph IV ANDA Certifications

50. If an ANDA applicant wishes to market its generic product for any approved FDA indication prior to the expiration date of a brand's Orange Book-listed patent, the ANDA applicant must file a Paragraph IV certification. The applicant must then provide the NDA holder and the patent owner with notice of its Paragraph IV certification, including a detailed description of the legal and factual bases for the ANDA holder's assertion that the patent is invalid, not infringed by the ANDA product, or is otherwise unenforceable. 21 U.S.C. § 355(j)(2)(B)(iii); 355(j)(2)(B)(iv)(II).

51. The filing of a Paragraph IV certification confers standing for the NDA holder to initiate patent litigation against the ANDA applicant (if such a suit otherwise would satisfy Fed. R. Civ. P. 11). If the NDA holder files suit within 45 days of receiving the Paragraph IV notice, it is entitled to a

regulatory stay of the FDA's ability to grant final approval to the ANDA for up to 30 months from the date the NDA holder received that notice. 21 U.S.C. § 355(j)(5)(B)(iii) (the "30-month stay").

52. Hence, the listing of even an invalid or commercially insignificant patent in the Orange Book affords the NDA holder a powerful tool to delay generic competition by up to 30 months.

D. The 180-Day Exclusivity Period for the First-to-File ANDA Applicant

53. The first generic manufacturer to file a substantially complete ANDA containing a Paragraph IV certification is eligible to receive 180 days of market exclusivity from the FDA. 21 U.S.C. § 355(j)(5)(B)(iv). During this window, the FDA may not grant final approval to any later-filed ANDA for the same drug. The exclusivity is triggered and begins to run when the FTF applicant commences commercial marketing, whether of its own ANDA-approved generic product or of an authorized generic sold pursuant to the brand NDA holder's NDA and distributed by the FTF.

54. Until the FTF applicant triggers its 180-day exclusivity by commencing commercial marketing, the exclusivity period remains "parked." A parked exclusivity functions as a bottleneck: no subsequent ANDA applicant can obtain final FDA approval while the FTF's exclusivity sits untriggered. This creates a powerful incentive for the brand manufacturer to induce the FTF applicant to delay commercial marketing, thereby perpetuating the bottleneck and forestalling generic competition from all ANDA filers, not just from the FTF.

55. Congress recognized this potential for abuse and enacted statutory forfeiture provisions to prevent an FTF applicant from parking its exclusivity indefinitely. Under 21 U.S.C. § 355(j)(5)(D)(i), the FTF's 180-day exclusivity is subject to forfeiture upon the occurrence of any of certain enumerated events. Two forfeiture provisions are particularly relevant here.

56. The first is the "Failure to Market" forfeiture. Under 21 U.S.C. § 355(j)(5)(D)(i)(I), the FTF applicant's exclusivity is forfeited if the FTF fails to market the drug within 75 days after the date on which its ANDA approval is made effective, or after the date of a court judgment, upheld on appeal, finding the relevant patents unenforceable, invalid or uninfringed by any applicant, whichever of these two dates comes later. In practical terms, once any ANDA applicant obtains a final court judgment from which no appeal can or has been taken (other than to the Supreme Court), of invalidity or

noninfringement of the patents qualifying the FTF for exclusivity, the 30-month litigation stay lifts and, typically, the applicant becomes eligible for approval, but for the existence of the FTF's 180-day exclusivity. From that moment, the FTF faces a "use it or lose it" deadline: if it does not begin commercial marketing within 75 days of that judgment of invalidity or noninfringement obtained by the subsequent applicant, the FTF's exclusivity is forfeited, and the bottleneck on all subsequent ANDA filers breaks.

57. The second is the "Failure to Obtain Timely Approval" forfeiture. Under 21 U.S.C. § 355(j)(5)(D)(i)(IV), the FTF's exclusivity is forfeited if the FTF fails to obtain tentative approval of its ANDA within 30 months of the date of its submission to the FDA, unless that failure is caused by a change in or a review of the requirements for approval imposed after the date on which the ANDA was filed. Tentative approval means the FDA has determined that the ANDA meets all applicable safety, efficacy, and labeling requirements, but that final approval is deferred because of a pending 30-month litigation stay or an unexpired FTF exclusivity period belonging to another ANDA applicant. This forfeiture provision is designed to flush out dormant applications and prevent an FTF from parking its exclusivity when it cannot realistically bring its product to market.

58. The Failure to Obtain Timely Approval forfeiture provision contains an important exception: if the FTF's failure to obtain tentative approval is attributable to the FDA's own change in, or review of, the requirements for approval after the ANDA was filed, forfeiture does not occur. This exception can insulate an FTF from forfeiture when the FDA has shifted its approval standards midstream, leaving every subsequent ANDA filer bottlenecked behind a parked exclusivity with no means to dislodge it absent a court judgment on the merits. Once the exception is applied, an ANDA filer can never forfeit under the Failure to Obtain Timely Approval forfeiture provision. This is a significant loophole to the forfeiture provisions that some drug manufacturers have begun to exploit to bottleneck non-FTFs' ANDAs behind the FTF's 180-day exclusivity. Here, according to the FDA, Actavis did not forfeit for Failure to Obtain Timely Approval, despite not having obtained tentative approval within 30 months of filing its ANDA in June 2015. Accordingly, the exception to this forfeiture provision must have applied.

59. Critically, a stipulated dismissal of Paragraph IV Hatch-Waxman litigation without a final court judgment on the merits does not trigger the Failure to Market forfeiture provision. Accordingly, insofar as the brand manufacturer can induce subsequent ANDA filers to abandon their patent challenges short of final judgment, the brand can preserve the bottleneck against all generic competition for as long as the FTF's exclusivity remains parked.

E. Authorized Generics

60. An authorized generic, or AG, is a drug sold under a brand manufacturer's NDA, rather than under an ANDA, but marketed and sold as a generic substitute. An NDA holder may sell an AG itself or may authorize a third party to do so by supplying the third party with AG to sell. Because an AG is distributed pursuant to an NDA rather than an ANDA, it does not require separate or additional FDA approval because the existing NDA for the brand product applies to the AG.

61. Because an AG is not an ANDA product, the FTF applicant's 180-day exclusivity does not prohibit its marketing. The brand and its partners are free to sell the AG in direct competition with the FTF's generic during that 180-day window. This can substantially erode the FTF's first-mover profits and dilute the expected value of the 180-day exclusivity.

62. Conversely, a brand manufacturer's commitment not to launch an AG during all or part of the FTF's 180-day exclusivity period — a No-AG commitment — has substantial economic value to the FTF. Without competition from the brand's own AG, the FTF is the sole generic seller during its exclusivity window and can capture all generic sales at a higher price in the absence of additional generic competition. The Supreme Court recognized in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), that the majority of the FTF's profits come from the 180-day exclusivity, so a No-AG commitment can constitute a "large and unjustified" reverse payment for purposes of antitrust analysis. Specifically, by declining to compete against the FTF with its own AG, the brand effectively transfers to the FTF the economic value of an uncontested generic monopoly.

63. When a brand partners with an ANDA filer to sell an AG, that also constitutes a transfer of value from the brand to a generic (FTF or otherwise). By making an ANDA filer the AG partner in exchange for the ANDA filer shelving its ANDA, the brand effectively removes one incremental

competitor from the market, ensuring that the AG partner maintains a higher market share and that it can sell at a higher price, because additional incremental competitors fight for market share by reducing price.

64. A brand will typically allow the AG to be sold only once the FTF launches under its ANDA, in order to compete with the FTF during its 180-day exclusivity and recapture some of the sales lost to generic competition. The brand typically has no incentive to launch an AG before such ANDA generic competition starts, because to do so would simply cannibalize sales that would otherwise remain with the brand, which is against the brand company's unilateral economic interests. Such conduct does make sense, however, in the context of a scheme or conspiracy that would enable the brand to sell its monopoly product in the absence of any generic competition for longer than it otherwise would because the brand typically sells at a substantially higher price than the generic.

F. The Economics of Generic Competition

65. Because bioequivalent and pharmaceutically equivalent (*i.e.*, AB-rated) generic versions of brand-name drugs contain the same API and are determined by the FDA to be just as safe and effective as their branded counterparts, the only material differences between generic drugs and their branded counterparts are their prices and manufacturers. Because generic versions of branded products are commodities that cannot be differentiated, the primary basis for generic competition is price.

66. Typically, generics are at least 10% less expensive than their branded counterparts when there is a single generic competitor. The generic price drops dramatically in multi-source competition. Thus, if a generic were the only generic product on the market, the generic would sell for a much higher price than if faced with additional generic competitors. Generic purchases rapidly replace brand purchases as a result of this price differential and because of automatic brand-to-generic substitution by pharmacies when filling prescriptions. Consequently, the launch of generic drugs typically results in significant cost savings to all drug purchasers and a precipitous loss in profits to the maker of the brand drug.

67. Since the passage of the Hatch-Waxman Act, every state has adopted substitution laws that either require or permit pharmacists to substitute AB-rated generic equivalents for branded prescriptions when filling prescriptions.

68. Several factors, including the regulatory interchangeability of bioequivalent AB-rated generics for the brand and state substitution laws, combine to produce the typical phenomenon that once a brand drug "goes generic," the product swiftly moves from a monopoly-priced to a commodity-priced item.

69. Generic competition enables all members of the chain of distribution including direct purchasers like the Plaintiff to purchase the drug at substantially lower prices. Until a genuine, independently competing generic version of the brand drug enters the market, however, there is no true bioequivalent substitute to compete with the brand, and the brand manufacturer can continue to charge supracompetitive prices. Brand manufacturers are well aware of this dynamic and the precipitous price erosion that genuine generic competition brings. They therefore seek to extend their monopolies through any means possible, sometimes resorting to illegal means.

VI. FACTS

A. The Rytary Orange Book Patents

70. Rytary (carbidopa and levodopa extended-release capsules) is an oral pharmaceutical formulation indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication. Rytary is approved in four strengths: 23.75 mg (carbidopa)/95 mg (levodopa), 36.25 mg/145 mg, 48.75 mg/195 mg, and 61.25 mg/245 mg.

71. On December 21, 2011, Impax submitted New Drug Application No. 203312 to the FDA for Rytary. The FDA approved Rytary on January 7, 2015. United States sales of branded Rytary have been in the hundreds of millions of dollars annually in recent years.

72. Impax listed nine patents covering Rytary in the Orange Book under NDA No. 203312, with listing dates and expiry dates as follows:

Patent No.	Title	Listing Date	Expiry
7,094,427 (’427)	Combination immediate release controlled release levodopa/carbidopa dosage forms	Mid-2015	May 29, 2022
8,377,474 (’474)	Controlled release formulations of levodopa and uses thereof	Jan. 27, 2015	Dec. 26, 2028
8,454,998 (’998)	Controlled release formulations of levodopa and uses thereof	Jan. 27, 2015	Dec. 26, 2028
8,557,283 (’283)	Controlled release formulations of levodopa and uses thereof	Jan. 27, 2015	Dec. 26, 2028
9,089,607 (’607)	Controlled release formulations of levodopa and uses thereof	Aug. 10, 2015	Dec. 26, 2028
9,089,608 (’608)	Controlled release formulations of levodopa and uses thereof	Aug. 10, 2015	Dec. 26, 2028
9,463,246 (’246)	Controlled release formulations of levodopa and uses thereof	Oct. 12, 2016	Dec. 26, 2028
9,533,046 (’046)	Controlled release formulations of levodopa and uses thereof	Jan. 11, 2017	Dec. 26, 2028
9,901,640 (’640)	Controlled release formulations of levodopa and uses thereof	Feb. 28, 2018	Dec. 26, 2028

73. None of the above listed patents was valid, nor were they infringed by any ANDA.

74. Of these nine patents, only the six issued and listed in the Orange Book at the time Actavis submitted its first-to-file ANDA in mid-2015 (the ’427, ’474, ’998, ’283, ’607, and ’608 patents) are “qualifying patents” that make Actavis eligible for 180-day exclusivity. Under the Medicare Modernization Act, only patents to which a first applicant submitted a Paragraph IV certification on the first day it filed a substantially complete ANDA can qualify the first applicant for 180-day exclusivity. The ’246, ’046, and ’640 patents, which were each listed after Actavis filed its ANDA, are not qualifying patents and therefore cannot automatically bottleneck other generics behind Actavis’s 180-day exclusivity.

B. The Actavis and Zydus Rytary ANDAs and the FDA Approval Bottleneck

75. Several generic manufacturers submitted ANDAs to the FDA seeking approval to market AB-rated generic versions of Rytary, each containing at least one Paragraph IV certification.

76. Actavis submitted ANDA No. 208522 for a generic Rytary in June 2015. Actavis was the first applicant to submit a substantially complete ANDA containing a Paragraph IV certification for Rytary, qualifying it as the first-to-file for purposes of the 180-day exclusivity. As FTF, Actavis's 180-day exclusivity is the bottleneck behind which all subsequent filers' ANDAs are stuck.

77. Zydus submitted ANDA No. 210911 for a generic Rytary on August 25, 2017. Zydus received an initial tentative approval on March 27, 2020, and a reissued tentative approval on July 30, 2020.

78. The FDA's Paragraph IV Patent Certifications List – a list that FDA publishes identifying drug products for which one or more substantially complete ANDAs containing a Paragraph IV certification have been submitted to FDA – reflects that Actavis's original first-to-file submission for Rytary occurred on June 10, 2015 (for the 61.25 mg/245 mg strength) and June 24, 2015 (for the 23.75 mg/95 mg, 36.25 mg/145 mg, and 48.75 mg/195 mg strengths). It also reflects an FDA "Non-Forfeiture" determination, with a 180-day decision posting date of August 10, 2020, meaning that FDA determined that Actavis has not forfeited its 180-day exclusivity for Failure to Obtain Timely Approval.

79. The FDA has expressly determined that Sandoz's and Zydus's ANDAs are not eligible for final approval because of the bottleneck created by Actavis's parked 180-day exclusivity. As to Zydus, the July 30, 2020 tentative approval letter for ANDA No. 210911 states that Zydus's ANDA satisfies all FDA requirements, but final approval is foreclosed by an earlier filer's exclusivity:

> We have completed the review of this ANDA, and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. . . . However, we are unable to grant final approval to your ANDA at this time. Prior to the submission of your ANDA, another applicant or applicants submitted a substantially complete ANDA providing for [Rytary] and containing a paragraph IV certification. Your ANDA will be eligible for final approval on the date that is 180 days after the commercial marketing date identified in section 505(j)(5)(B)(iv) of the FD&C Act.

80. The Sandoz tentative approval letter contains materially identical bottleneck language. The FDA's determination confirms that the only impediment to robust generic competition for Rytary is the parked Actavis exclusivity.

C. The Impax-Actavis Litigation

81. On September 17, 2015, Impax filed a Hatch-Waxman patent suit against Actavis in the United States District Court for the District of New Jersey, captioned *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc., et al.*, Civil Action No. 2:15-cv-06934-SRC-CLW (D.N.J.).

82. The Impax-Actavis litigation went very poorly for Impax. On March 8, 2018, Judge Chesler granted summary judgment of noninfringement in favor of Actavis on twenty-eight of the thirty-seven asserted claims across four patents. Specifically, the Court granted Actavis summary judgment as to: (i) all claims of infringement of claim 21 of the '608 patent; (ii) all claims of literal infringement of claims 1, 2, 3, and 5 of the '283 patent; (iii) all claims of literal infringement of claims 5, 8, 10, 13, 17, 18, and 19 of the '608 patent; (iv) the issues of direct, literal infringement of claims 1, 9, 14, 17, 19, 21, 25, 49, 51, and 53 of the '246 patent; and (v) the issues of direct, literal infringement of claims 7, 12, 14, 16, 18, and 31 of the '046 patent. *See Impax Labs., Inc. v. Actavis Labs. FL, Inc.*, No. 2:15-cv-06934 (SRC), 2018 WL 1863826 (D.N.J. Apr. 18, 2018) (as amended).

83. The remaining claims proceeded to a bench trial before Judge Chesler beginning May 14, 2018. Trial concluded on May 17, 2018.

84. Impax was at significant risk of losing the trial. As referenced above, as to one set of claims, Judge Chesler had already wiped out Impax's main infringement allegation, saying it was based on a "sky is green" theory. *Impax*, 2018 WL 1863826, at *4. Impax was left with a backup infringement argument relating to the doctrine of equivalents, but that argument was subject to similar flaws in reasoning to those Judge Chesler had already found meritless. For example, that it would vitiate the same "distinct bead" limitation on which Impax had *already* tried to avoid with its "sky is green" argument.

85. As to another set of claims, Judge Chesler had similarly already wiped out Impax's main infringement theory, noting that even if Impax had presented a viable legal theory (it hadn't), it had presented no evidence that Impax's "proposed special analytic procedure" had been used. *Id*. at *9. Here, too, Impax was left only with tertiary arguments relating to the doctrine of equivalents and indirect infringement. Moreover, Actavis asserted viable invalidity defenses relating to 35 U.S.C. § 112 that not

only constrained Impax's infringement arguments, but also posed significant risk of further harming what little was left of the Rytary patent estate.

86. On June 20, 2018, before Impax was forced to respond to Actavis's arguments in post-trial briefing, Amneal, which had recently completed its acquisition of Impax, and Actavis announced that they had settled the litigation. Amneal's press release stated:

> Under the terms of the agreement, Amneal will grant Actavis a license to begin selling a generic version of Rytary on July 31, 2025, or earlier under certain circumstances. Additional details regarding the settlement were not disclosed. The launch of Actavis's generic product is contingent upon Actavis receiving final approval from the FDA of its ANDA for a generic version of Rytary.

The case was terminated on June 25, 2018.

87. The Impax-Actavis settlement, executed despite Actavis's favorable summary judgment outcome and the strong likelihood that Actavis would prevail at trial, included a launch date for Actavis that was more than seven years away. The seven-year delay to Actavis's launch date is not explained by the strength of Impax's patents, which were extraordinarily weak. Rather, it is explained by the No-AG reverse payment promise from Impax.

D. The 80-Day Actavis No-AG Reverse Payment Agreement

88. The Impax-Actavis agreement contained a commitment by Impax that Actavis would not face competition from an AG version of Rytary for a period of at least 80 days following Actavis's licensed entry date of July 31, 2025. As set forth above, such a No-AG commitment transfers substantial economic value from the brand manufacturer to the FTF.

89. Although Impax concealed this No-AG term, its existence and duration are established by the comparison of two publicly announced dates. First, Amneal's June 20, 2018 press release announced that Actavis was licensed to begin selling generic Rytary on July 31, 2025. Second, Zydus launched AG Rytary on October 20, 2025, 81 days after Actavis's agreed-upon entry date. Because it would otherwise be in both Zydus's and Impax's interests to begin selling AG Rytary on the first day of Actavis's license, the 80-day delay resulted from the terms of the preceding Impax-Actavis agreement. Although the majority of the license terms in both the Impax-Actavis and Impax-Zydus agreements have never

been disclosed, the 80-day difference between the two publicly announced dates is the fingerprint of the concealed No-AG commitment in the Impax-Actavis settlement.

90. The No-AG commitment conveyed enormous expected value to Actavis. An FTF generally earns the majority of its total profits on a generic drug during its 180-day exclusivity period, and an authorized generic launched during that period will typically capture half or more of generic unit sales while also driving down generic prices. The FTC has found "strong evidence that agreements not to compete with an authorized generic have become a way for brand-name companies to compensate generic competitors for delaying entry," and that an FTF's revenues approximately double during the first six months of generic competition when the FTF is free from AG competition. FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* at vi (Aug. 2011). The Supreme Court has likewise recognized that the right to sell as the sole generic "can prove valuable, possibly worth several hundred million dollars." *Actavis*, 570 U.S. at 144. Accordingly, Impax's commitment that Actavis would sell free of AG competition for at least the first 80 days following its entry was worth far in excess of any litigation costs Impax avoided by settling.

91. The No-AG commitment was unjustified. Actavis had no patent or statutory right to be free from competition from an authorized generic. The commitment was not compensation for avoided litigation expenses or for any services Actavis provided to Impax. Its only function was to compensate Actavis for accepting a licensed entry date more than seven years away, a delay wholly untethered to the strength of Impax's patents, which had already been gutted at summary judgment. A No-AG commitment of this kind constitutes a large and unjustified reverse payment under *Actavis* and its progeny.

92. Absent the reverse payment, Actavis would have prevailed in its Hatch-Waxman litigation against Impax and cleared the path for generic competition. Instead, purchasers had to wait until October 20, 2025 for the opportunity to purchase AG Rytary from Zydus – an opportunity further delayed from the already delayed July 31, 2025 Actavis licensed entry date.

93. There is no plausible cognizable procompetitive justification for the Impax-Actavis arrangement. The agreement promised a transfer of value from Impax to Actavis far in excess of any

saved litigation costs in exchange for Actavis's abandonment of a patent challenge that was about to succeed and that would have opened the Rytary market to robust generic competition.

94. The No-AG payment Impax agreed to provide to Actavis and the AG license to Zydus were mutually reinforcing components of a single anticompetitive scheme. The No-AG commitment induced Actavis to accept the seven-year delay that created the bottleneck; the bottleneck in turn made the Zydus AG license valuable enough to induce Zydus to abandon the litigation that would have broken the bottleneck; and the Zydus AG launch was itself scheduled around Actavis's protected 80-day window. Each aspect of the scheme preserved and enhanced the value of the other, at the expense of competition and of Rytary purchasers.

E. The Impax-Zydus Litigation

95. It was public knowledge that Actavis had not obtained FDA approval, so Zydus saw an opportunity to break the Actavis bottleneck by forcing Actavis's forfeiture via the Failure to Market provision, and to launch its own generic product as soon as possible. On August 25, 2017, Zydus submitted ANDA No. 210911 to FDA, containing Paragraph IV certifications to each of the eight then-listed Rytary patents.

96. On December 21, 2017, within 45 days of receipt of a Paragraph IV certification letter from Zydus, Impax filed a Hatch-Waxman suit against Zydus in the District of New Jersey, captioned *Impax Laboratories, Inc. v. Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited*, Civil Action No. 2:17-cv-13476-SRC-CLW (D.N.J.). The complaint alleged infringement of only the '608 patent. Impax declined to assert the '427, '474, '998, '283, '607, '246, '046, and '640 patents (the '640 patent was listed after the litigation started).

97. On April 27, 2018, Zydus filed an Amended Answer asserting counterclaims for declaratory judgments of noninfringement and invalidity. Zydus pursued counterclaims as to the six patents that were issued and Orange-Book listed at the time of Actavis's ANDA submission and that therefore qualified Actavis for 180-day exclusivity (the '427, '474, '998, '283, '607, and '608 patents). Zydus did not need to obtain a noninfringement judgment as to the '246, '046, or '640 patents to trigger Actavis's Failure to Market forfeiture, because those three patents had not been issued and listed at the

time of Actavis's ANDA submission and therefore did not qualify Actavis for 180-day exclusivity. In addition, each of the '246, '046, or '640 patents was invalid and/or non-infringed for reasons similar to the patents that were actually litigated.

98. In its counterclaims, Zydus expressly recognized the bottleneck mechanics that motivated its patent challenge:

a. "In an effort to prevent a first filer from indefinitely preventing subsequent filers from entering the market, the Hatch-Waxman act provides that a first filer may forfeit its 180-day marketing exclusivity under certain circumstances." *Impax Laboratories, Inc. v. Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited*, Civil Action No. 2:17-cv-13476-SRC-CLW (D.N.J.), ECF No. 17, ¶ 12.

b. "[A] first filer will forfeit its exclusivity if it fails to market its product . . . 75 days after a subsequent ANDA filer (who has tentative approval for its ANDA from FDA) obtains a final decision of noninfringement or invalidity as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period." *Id.* ¶ 13.

c. "On information and belief, as of April 27, 2018, Actavis has not received tentative or final approval for its ANDA, it has been more than thirty months since Actavis submitted its ANDA, and FDA has not made a formal determination of Actavis's eligibility for 180-day exclusivity." *Id.* ¶ 26.

d. "A judicial determination of invalidity and/or noninfringement of the '427, '474, '998, '283, and '607 patents in Zydus's favor could affect the timing of Zydus's commercial manufacture, use, or sale of its proposed ANDA products, as such a decision could affect when the first filer must market its product or otherwise forfeit any 180-day marketing exclusivity that it may have." *Id.* ¶ 37.

99. Impax answered Zydus's counterclaims on June 1, 2018. As to five of the six counterclaim patents, Impax admitted noninfringement, conceding for each that "[a]s of this date, based on the current proposed products that are the subject of ANDA No. 210911, Plaintiff admits" noninfringement. *Id*. ECF No. 31.

100. On the basis of those admissions, Zydus moved for judgment on the pleadings under Federal Rule of Civil Procedure 12(c). *Id.* ECF No. 57.

101. On November 29, 2018, Judge Chesler granted Zydus's Rule 12(c) motion in full and entered judgment of noninfringement in Zydus's favor on counterclaim Counts III, V, VII, IX, and XI. *Id.* ECF Nos. 102 (Opinion) and 103 (Order). The Court ordered "that the subject of ANDA No. 210911, as of June 1, 2018, does not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of U.S. Patent Nos. 7,094,427; 8,377,474; 8,454,998; 8,557,283; and 9,089,607." *Id.* ECF No. 103. With those five patents removed from the case, only a single claim of the '608 patent, the lone patent left preserving the Actavis bottleneck, remained for trial. Given Impax's repeated failure to show infringement, its chances were dim. And again, Impax faced a vigorous invalidity defense by Zydus that both constrained Impax's infringement arguments and further risked invalidation.

102. By early 2020, Zydus was poised to break the Actavis bottleneck. The 30-month statutory stay on FDA approval of Zydus's ANDA, triggered by Impax's December 2017 suit, expired on or about May 6, 2020. A bench trial on the '608 patent was scheduled to begin on April 6, 2020.

103. On March 23, 2020, Judge Chesler issued an order denying the parties' motions *in limine*, and on the same day adjourned the April 6, 2020 trial without rescheduling it. *Id.* ECF No. 211; Mar. 23, 2020 docket notification.

104. On May 18, 2020, Impax and Zydus jointly moved to dismiss the action without prejudice. *Id.* ECF No. 212. Judge Chesler entered the proposed order the next day, May 19, 2020. *Id.* ECF No. 213. The parties issued no contemporaneous press release of any settlement. Had the parties not settled in May 2020, they would have reasonably expected to proceed to trial at that time instead.

105. On July 30, 2020, FDA granted Zydus tentative approval (reissued from the initial March 27, 2020 tentative approval) for ANDA No. 210911. The letter expressly identifies the cause of FDA's inability to grant final approval: not any deficiency in Zydus's ANDA, but Actavis's unexpired 180-day FTF exclusivity. The FDA wrote that it "completed the review of this ANDA, and ha[s] concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval," but could not grant final approval because "another applicant or applicants submitted a substantially complete ANDA . . . containing a paragraph IV certification" before Zydus did.

106. Absent the settlement, the anticipated May 2020 bench trial would have resulted in a decision in Zydus's favor. Assuming Actavis failed to market within 75 days of an unsuccessful appeal (if one were taken), Actavis's 180-day exclusivity would have been forfeited and the bottleneck dissolved. Zydus, armed with its tentative approval, could then have obtained final approval and launched its independent ANDA product by now. Other ANDA filers would have followed, and Impax would have launched its own generic to take sales from the generic manufacturers.

107. Zydus did not simply walk away from this winning case that would have allowed it to launch its generic product years ago; it was paid off by Impax to do so. While the exact contours of the agreement have been and remain hidden by Defendants, the outcome for Zydus is clear: Zydus has been able to sell an authorized generic version of Rytary free of generic competition because Impax has not launched a competing generic version, and all other generics remain bottlenecked by Impax's agreement with Actavis. As a result of its agreement to preserve this bottleneck, Zydus is positioned to be the lone generic on the market until patent expiry in December 2028 or until Actavis's 180-day exclusivity lapses, whichever comes first. Moreover, even if Actavis had launched, Zydus would have competed 81 days later as Impax's AG during Actavis's FTF exclusivity period without further competition from an AG or other tentatively approved ANDA generics, like Sandoz, an outcome Zydus could not have obtained by litigating. To secure its delay, Impax schemed to privilege Zydus at the expense of every other generic competitor and purchasers of Rytary.

F. Other ANDAs

108. Sandoz submitted ANDA No. 208895 for generic Rytary in December 2016.

109. On March 31, 2017, within 45 days of receipt of a Paragraph IV certification letter from Sandoz, Impax filed a Hatch-Waxman patent suit against Sandoz in the District of New Jersey, captioned *Impax Laboratories, Inc. v. Sandoz, Inc.*, Civil Action No. 2:17-cv-02227-SRC-CLW (D.N.J.).

110. The parties settled in or around December 2018, about six months after the Impax-Actavis agreement.

111. Additional generic manufacturers have submitted ANDAs, but they are all also bottlenecked behind Actavis's parked 180-day exclusivity. These include ANDAs from Zydus, Sandoz, Dr. Reddy's Laboratories, Ltd., Qilu Pharma Inc., Biocon (tentatively approved as of December 4, 2025), ScieGen Pharmaceuticals, Inc., and Ascent (tentatively approved as of February 18, 2025).

G. The Impax-Zydus Reverse Payment

112. The Impax-Zydus agreement that induced Zydus to abandon its litigation and efforts to break the Actavis bottleneck was a large and unjustified reverse payment.

113. Had Zydus litigated the '608 patent to judgment and prevailed, as it was on the verge of doing, and succeeded on appeal, as it would have, the resulting judgment of noninfringement or invalidity, combined with Zydus's tentative approval, would have started the 75-day Failure to Market clock against Actavis. Assuming Actavis (which still lacks tentative approval) failed to launch within 75 days, Actavis's 180-day exclusivity would have been forfeited.

114. The forfeiture would have broken the Actavis bottleneck, opening the Rytary market to genuine multi-generic competition. Absent the payment it received, Zydus would have entered as one of several competing generics, including Impax's own AG, as well as several subsequent ANDA filers who would have been economically incentivized to expedite their FDA approval and market entry.

115. Because Zydus would obtain a substantially lower share of generic sales and sell at a substantially lower price with more generics on the market, Zydus's expected revenues from litigating the '608 patent to judgment and winning, and launching its ANDA product in competition with other ANDA filers *and* an Impax AG would have been a fraction of what it will receive under its agreement with Impax whereby Zydus propped up the Actavis bottleneck and became the AG, thus reducing by at

least one the number of competitors on the market competing for market share and slashing prices. The value conveyed to Zydus in this manner is substantial and well in excess of Impax's avoided litigation costs.

116. Even assuming, *arguendo*, that the Impax-Actavis settlement was lawful, the Impax-Zydus agreement independently and substantially delayed generic competition. Absent that agreement, Zydus would have litigated the '608 patent to judgment, prevailed, triggered Actavis's Failure to Market forfeiture, and precipitated entry not just by Zydus's own ANDA generic product but by other bottlenecked filers regardless of the propriety of the Actavis settlement.

117. Actavis never did launch on July 31, 2025, and has not launched to date. Therefore, as of this Complaint, Actavis's 180-day exclusivity remains parked, and the bottleneck it created for every subsequent Rytary ANDA filer remains in place. By entering into a reverse payment agreement that erected a bottleneck, Impax's misconduct laid the foundation for the later unlawful Impax-Zydus agreement that maintained the bottleneck.

118. To date, Zydus has not launched its ANDA generic Rytary product, because its ANDA remains bottlenecked. Instead, on October 20, 2025, more than five years after FDA tentatively approved its ANDA, and 81 days after the agreed-upon Actavis launch date of July 31, 2025, Zydus started to sell AG Rytary (the brand product, under Zydus's trade dress). On information and belief, October 20, 2025 was a date certain fixed in the Impax-Zydus agreement so that Zydus's AG entry would fall just outside the 80-day No-AG window that Impax granted Actavis in the Impax-Actavis agreement, as set forth above.

119. Under the Impax-Zydus agreement, in exchange for quitting the patent fight and preventing the triggering of not just its own, but all generics' competition by breaking the Actavis bottleneck, Impax permitted Zydus alone to evade that bottleneck. Zydus's entry is free from competition from any ANDA product, because all such products, including Zydus's own, remain bottlenecked behind Actavis. Moreover, Zydus became the sole seller of a generic Rytary even though there is nothing in the law or regulations that would prevent Impax from competing with Zydus for

generic sales by selling or licensing a competing generic. In fact, it would be in Impax's unilateral economic interests to compete with Zydus to claw back some of the share it lost to Zydus.

120. The result is a market with a single generic, an economic impact identical to other No-AG reverse payment cases where the brand promises not to launch an AG to compete with the first filer during its 180-day exclusivity. But here, in contrast to other No-AG agreements that have been challenged under the antitrust laws, the fallout for the market is even worse because rather than a market with one generic for 180 days followed by robust competition thereafter, the bottlenecking scheme means that Zydus's AG can be the only generic on the market for over three years. The value of selling as the only generic on the market for over three years instead of competing with several other generics is a windfall for Zydus and far in excess of Impax's avoided litigation costs.

121. The unlawful scheme also fundamentally transformed Impax's and Zydus's competitive incentives. Before executing their collusive agreement, Zydus had every incentive to litigate and win: a judicial victory would have opened the market to generic competition including from Zydus's own ANDA product. Zydus would have profited from being able to sell its ANDA product freely. After entering its collusive agreement with Impax, Zydus had every incentive to preserve the bottleneck: so long as other ANDA filers remain bottlenecked, and so long as Impax continues to refrain from launching its own competing generic, Zydus's authorized generic faces no independent generic competition whatsoever. Zydus's interest shifted from breaking the Actavis bottleneck to preserving it.

122. All of Impax's conduct in connection with the AG for Rytary is against its unilateral economic interests. First, entering into an agreement to withhold AG from the market until after 80 days elapsed from the start of generic competition cedes all generic sales to the FTF for those 80 days. Second, permitting the launch of an AG into a market without other generics, as Impax in fact allowed, shifted sales from Impax's higher-priced brand product to the AG, just as Impax knew it would. Third, failing to compete with Zydus when there was nothing stopping it from doing so means that Impax unilaterally and irrationally ceded the entire generic market to Zydus.

123. Impax's economically irrational conduct makes sense, however, when factoring in several more years of monopoly profits on brand Rytary that Impax secured from its reverse payment

agreements with Actavis and Zydus. Impax's irrational acts were Impax making good on its promise to compensate Actavis and Zydus for delay.

124. When Impax had an opportunity to launch another generic to compete with Zydus's AG, it did not do so. This was due to an agreement, express or implied. Express agreements to restrict AG competition are widely recognized as anticompetitive. But not all such commitments take the form of an explicit written promise. *See* https://www.ftc.gov/enforcement/competition-matters/2025/01/reverse-payments-cash-quantity-restrictions-other-possibilities. Brand and generic manufacturers have increasingly structured AG licenses to achieve the same economic result as an express No-AG agreement through profit-sharing or volume-limitation provisions rather than through an express prohibition on AG launch. Under such arrangements, the brand does not formally agree to refrain from launching its own AG; instead, the economics of the agreement make launching a competing AG against the economic interest of the brand. These recent structures have negative effects on competition because they result in one fewer generic product on the market (and prolong the brand's monopoly when executed as part of an agreement on a delayed generic entry date).

125. Sometimes brand and generic companies use a royalty to achieve these results, by aligning the brand's financial interests with those of the AG licensee. If an agreement between the brand and a generic permits the generic to launch an AG, and the agreement has a royalty, it would be against the brand's interest to launch an additional generic, because the additional competition would cause a reduction in generic prices and the first AG's market share, thereby reducing the royalty payment. These factors would erode the royalty stream the brand would otherwise receive from the first AG. The brand's economic interest therefore is to limit competition to its royalty-paying licensee.

126. A volume limitation on an AG license restricts output and economically incentivizes the brand manufacturer to limit further competition to its royalty-paying licensee. By capping the units available to the AG licensee, the brand ensures that a portion of the market remains insulated from generic price competition regardless of the licensee's pricing decisions. In a genuinely competitive market, a generic manufacturer is unrestrained in volume and will supply the market up to its full demand, competing on price. A volume cap forecloses that dynamic and guarantees protected demand

for the brand's product above the generic cap. A brand has no incentive to introduce further generic supply into the market under such conditions.

127. Whether implemented through a royalty, a volume limitation, or both, these provisions share a single economic function: to ensure that generic entry does not produce the downward price discipline that true competition would produce. An agreement that pairs an AG license with a royalty and/or volume cap to create further incentives to suppress competition is therefore no less anticompetitive than one containing an explicit No-AG commitment, for example.

128. In its February 27, 2026 Annual Report, Amneal stated that "Our branded pharmaceutical products are or may become subject to competition from generic equivalents because either (i) there is no proprietary protection for some of the branded pharmaceutical products we sell, (ii) our patent protection expired or (iii) our patent protection is not sufficiently broad or enforceable. For example, in 2025, we lost exclusivity for RYTARY®, an extended-release oral capsule formulation of carbidopa-levodopa for the treatment of Parkinson's disease." If the Impax-Zydus agreement does contain either a royalty or a unit limitation, that would mean that Impax merely cut Zydus into its monopoly by giving it a small allocation thereof, and/or requiring that Zydus kick back a portion of its generic revenues in the form of a royalty that Impax would be incentivized not to undercut. The purported "loss of exclusivity" would really just be Impax cutting Zydus into its monopoly instead of competing in earnest.

129. There is no plausible cognizable procompetitive justification for the Impax-Zydus arrangement. The agreement transfers value from Impax to Zydus far in excess of any saved litigation costs in exchange for Zydus's abandonment of a patent challenge that was about to succeed and that would have removed the bottleneck and opened the Rytary market to robust generic competition.

130. As a direct result of Defendants' conduct, Plaintiff and the proposed Class paid hundreds of millions of dollars in supracompetitive prices for branded and/or generic Rytary that they would not have paid absent the reverse payment Impax made to Zydus.

VII. CLAIM ACCRUAL AND/OR TOLLING

131. Plaintiff's Complaint is timely as to all claims accruing within four years of the date of the filing of this Complaint.

132. Plaintiff's damages predating the four years immediately preceding the filing of this Complaint are also timely under the doctrines of equitable tolling, the discovery rule and fraudulent concealment.

133. These doctrines apply because (1) Defendants concealed from Plaintiff the existence of this cause of action; (2) Plaintiff remained in ignorance of this cause of action until some point within four years of the commencement of this action; and (3) Plaintiff's continuing ignorance was not attributable to lack of diligence on its part.

134. Defendants concealed from Plaintiff the existence of their cause of action.

135. Specifically, on or around June 2018, negotiators representing Impax and negotiators representing Actavis agreed on the terms of the challenged agreement in connection with settlement of their ongoing Hatch-Waxman patent dispute.

136. Impax and the negotiators representing it concealed from Plaintiff the terms of the agreement pursuant to which Impax agreed, expressly or impliedly, not to compete with Actavis with an AG after Actavis launched its generic, a common form of "pay-for-delay." The agreement or agreements containing that illegal term were private agreements to which neither the Plaintiff nor any Class Member was a party. Without the benefit of insider information about the content of those agreements, there was no way for Plaintiff to know or discover that it and the Class Members were being overcharged until Zydus launched its AG on the 81st day after Actavis's July 31, 2025 licensed entry date. There was no public court filing, press release or SEC filing disclosing this term. The Defendants kept the illegal agreement terms secret until the generic launch patterns described herein made it clear that the challenged agreement contains an express or implied No-AG clause.

137. Plaintiff remained in ignorance of this cause of action until some point within four years of commencement of this action and its continuing ignorance was not attributable to a lack of diligence on its part.

138. Specifically, Plaintiff had insufficient knowledge of the Defendants' anticompetitive conduct to file an antitrust claim until after the launch of Zydus's AG on October 20, 2025. It was only

after this launch that there was sufficient evidence that an antitrust violation (an agreed upon payment to Actavis in the form of a No-AG term) had occurred.

139. Because Defendants concealed this illegal No-AG term, there was no way to know about it until Zydus launched the AG.

140. Drug manufacturers typically communicate with Plaintiff about pending generic launches. The manufacturers provide this information so that Plaintiff can stock drug products as soon as it is available in order to meet the demand of its pharmacy customers. Here, Plaintiff detected no suspicious conduct prior to the launch of Zydus's AG Rytary.

141. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations for the Plaintiff's and the Class's claims have been tolled.

142. Alternatively, if the statute of limitations is not tolled, this Complaint alleges a continuing course of conduct (including conduct within the limitations period), and Plaintiff and members of the Class can recover for overcharges by Defendants that they suffered during the limitations period.

VIII. CLASS ACTION ALLEGATIONS

143. Plaintiff, on behalf of itself and all other similarly situated direct purchasers, seeks damages, measured as overcharges, trebled, against Defendants for their anticompetitive conduct in the market for carbidopa and levodopa capsules in the 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, and 61.25 mg/245 mg strengths (Rytary and its generic equivalents).

144. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(3), as representatives of a class of direct purchasers (the "Class") defined as follows:

> All persons who or entities which purchased in the United States[3]: Rytary or generic Rytary (including authorized generic Rytary) directly from Impax or Zydus at any time on or after August 2020 through the present and until the anticompetitive effects of Defendants' conduct cease (the "Class Period").
>
> Excluded from the Class are Defendants and their respective officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

[3] The term "United States" includes all fifty states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any other territories or possessions of the United States.

145. Members of the Class are so numerous that joinder is impracticable. Further, the Class is readily identifiable from information and records in Defendants' possession.

146. Plaintiff's claims are typical of those of the Class. All Class Members were damaged by the same wrongful conduct of Defendants – *i.e.*, they paid artificially inflated prices for brand and/or generic Rytary and were deprived of earlier and more robust competition from less-expensive generic Rytary as a result of Defendants' wrongful conduct.

147. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

148. The Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular expertise in pharmaceutical antitrust class actions.

149. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual class members because Defendants have acted on grounds generally applicable to the entire Class thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

150. Questions of law and fact common to the Class include:

i. whether Impax willfully obtained and/or maintained monopoly power over Rytary;

ii. whether Impax's scheme to monopolize, either in whole or in part, violated Section 2 of the Sherman Act;

iii. whether Impax conspired with Actavis to monopolize the market for Rytary;

iv. whether Impax conspired with Zydus to monopolize the market for Rytary;

v. whether Impax agreed to make a large unlawful reverse payment to Actavis in 2018 in exchange for Actavis's agreement to delay generic entry at least through July 31, 2025;

vi. whether Impax made a large unlawful reverse payment to Zydus in 2020 in exchange for Zydus's agreement to delay generic entry at least through October 20, 2025;

vii. whether Impax's reverse payment agreements violated Section 1 of the Sherman Act;

viii. whether the agreements between Impax and Actavis and Impax and Zydus constituted an agreement to allocate markets that is a *per se* violation of the Sherman Act;

ix. whether Impax's agreements with Actavis and Zydus perpetuated an FDA approval bottleneck that unlawfully prevented the FDA from approving any other would-be generic versions of Rytary;

x. when, in the absence of the unlawful conduct alleged herein, generic Rytary entry would have occurred;

xi. whether Defendants' activities substantially affected interstate commerce;

xii. whether, and, if so, to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to the Plaintiff and the Class; and

xiii. the quantum of aggregate overcharge damages to the Class.

151. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweigh potential difficulties in management of this class action.

152. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

IX. MARKET POWER AND DEFINITION

153. The relevant geographic market is the United States. The relevant product market is brand and generic Rytary (including AG Rytary). The relevant antitrust market is brand and generic Rytary (including AG Rytary) sold in the United States and its territories and possessions.

154. Prior to AG entry, Impax's share of the Rytary relevant antitrust market was 100%. After the Zydus AG launch, Impax and Zydus collectively had 100% of the relevant antitrust market.

155. At all relevant times, Impax had monopoly power in the market for Rytary, consisting of Rytary and its generic equivalents (including AG Rytary). It had the power to and did maintain the price of Rytary at supra-competitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Rytary, with the exception of AB-rated generic Rytary. This market power may be shown directly, and therefore no relevant market needs to be defined.

156. Manufacturers attempt to differentiate brand name drugs like Rytary based on features and benefits (including safety and efficacy), and not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Rytary. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Rytary.

157. Other products are not practical substitutes for Rytary and its respective AB-rated generic substitutes. During the relevant period, other forms of similarly-indicated drug therapies have been freely available, but the presence of these alternatives did not result in lower Rytary prices.

158. Other various non-Rytary Parkinson's treatments may exist, but none exhibits cross price elasticity with Rytary and therefore do not and did not constrain its price at all relevant times. The existence of these other products that may be used to treat similar indications did not constrain Impax's ability to raise or maintain Rytary prices without losing substantial sales, and therefore those other drug products are not in the same relevant antitrust market as Rytary. Therapeutic alternatives, to the extent existent, are not the same as economic alternatives.

159. Functional similarities between Rytary and other similarly-indicated medicines other than AB-rated generic Rytary equivalents, are insufficient to permit inclusion of those other molecules in the relevant market with Rytary. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would otherwise be maintained in a competitive market. At all relevant times, no other similarly-indicated medication (except for AB-rated generic versions of Rytary) has or will take away sufficient sales of Rytary to prevent Impax from raising or maintaining the price of Rytary above levels that would otherwise prevail in a competitive market.

160. Rytary is also not reasonably interchangeable with any products other than its respective AB-rated generic counterparts because Rytary has significantly differentiating attributes making it a unique drug product. The FDA does not consider Rytary interchangeable with any other medication other than its AB-rated generic equivalents.

161. Impax needed to control only Rytary and its respective AB-rated generic equivalents, and no other products, to maintain the price of Rytary at a supracompetitive level while preserving all or virtually all of its sales. Only the market entry of a competing, AB-rated generic version of Rytary would render Impax unable to maintain its monopoly prices of Rytary without losing substantial sales.

162. Impax also sold Rytary at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins, direct evidence of Impax's monopoly power.

163. Impax has exercised its power to exclude and restrict competition to Rytary and its respective AB-rated generic equivalents.

164. Impax, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due, in large part, to legally and illegally created patent protections, legally and illegally created regulatory bars to FDA approval of generic competitors, and high costs of entry and expansion.

165. To the extent Plaintiff is legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, Plaintiff alleges that the relevant

market is carbidopa and levodopa capsules in the 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, and 61.25 mg/245 mg strengths (*i.e.*, Rytary and its respective AB-rated generic equivalents). During the period relevant to this case, Impax has been able to profitably maintain the price of Rytary well above competitive levels.

X. MARKET EFFECTS AND CLASS DAMAGES

166. Absent the anticompetitive conduct alleged above, multiple generic manufacturers would have entered the market with their generic versions of Rytary years ago because absent Impax's monopolization scheme and its reverse payments, the FDA would have likely started approving Rytary ANDAs for immediate market entry years ago. Alternatively, Impax would have entered into agreement(s) with earlier generic entry and without reverse payment(s). Generic entry would have started by August 2020, and so Plaintiff incurred damages on their purchases of Rytary starting in August 2020. Specifically, the Actavis trial was completed by May 2018 and a decision would have been expected by about November 2018. Following the inevitable Actavis victory, any Impax appeal would have lasted about 18 months until a decision by approximately May 2020. Actavis would then have 75 days to launch under the Failure to Market provision, at which point generic sellers would have launched, in about August 2020.

167. Instead, Impax willfully and unlawfully maintained its monopoly power in the market for Rytary through its scheme to exclude competition. The scheme delayed generic competition and carried out its anticompetitive effect of maintaining supracompetitive prices for Rytary. Impax implemented its scheme by, among other things: (i) settling its Paragraph IV Hatch-Waxman litigation with Actavis, the first Rytary generic ANDA filer, with an unlawful reverse payment in the form of an 80-day No-AG commitment; (ii) erecting an improper FDA approval bottleneck thereby; (iii) settling its Paragraph IV Hatch-Waxman litigation with Zydus with an unlawful reverse payment that induced Zydus not to break that bottleneck and not launch generic Rytary, by giving Zydus as much as a 100% monopoly of the generic Rytary market as a sales partner starting in October 2025. These acts, individually and/or in combination, were anticompetitive.

168. By June 2018, Actavis was threatening to usher in generic competition for Rytary. It had already obtained summary judgment of noninfringement on twenty-eight of the thirty-seven claims Impax asserted across four patents, leaving Impax with only tertiary infringement theories, and the parties had tried the case to conclusion, with a decision imminent. Actavis's imminent litigation victory meant that Impax faced a judgment that would have permitted ANDA filers clearance to start competing. Absent some inducement to abandon that posture, Actavis had every incentive to continue to try to get FDA approval and launch years before July 31, 2025. Impax supplied that inducement: the concealed commitment that no authorized generic would compete with Actavis for at least the first 80 days following its licensed entry.

169. Rather than pursue its winning litigation position, Actavis agreed to dismiss the litigation and to forego entry into the Rytary market for more than seven years. In exchange, Actavis received Impax's commitment that no authorized generic would compete with Actavis for at least the first 80 days following its licensed entry. By accepting these terms, Actavis agreed to horizontally allocate markets with Impax: Actavis would cede the entire Rytary market to Impax's brand monopoly until July 31, 2025, and Impax would in turn cede the generic segment of the market exclusively to Actavis for at least the first 80 days following Actavis's entry. The agreement also made Actavis's parked exclusivity the instrument of a broader anticompetitive scheme: it became the bottleneck that blocked FDA approval of every other Rytary ANDA, suppressing independent generic competition from all subsequent filers for Impax's and Actavis's joint benefit.

170. Impax's scheme to induce Actavis to abandon its litigation position and enter into this market allocation caused independent harm to the Class. Had Actavis pressed its advantage to judgment (the likely outcome), ANDA filers would have obtained FDA approval and launched by now. Multiple competitively priced generics would have entered the market years earlier and competed on price against Rytary and against one another. Instead, Actavis agreed to suppress competition and preserve supracompetitive pricing at the expense of members of the Class who have been overcharged on their purchases of brand and generic Rytary from Defendants.

171. By May 2020, Zydus occupied a uniquely threatening competitive position. It had already obtained a judgment of noninfringement on five of the six Impax patents asserted against it, leaving only the '608 patent for trial. Zydus's near-complete litigation victory meant that it was the only generic ANDA filer positioned to break Actavis's FTF bottleneck: a Zydus judgment on the '608 patent would have threatened Impax's ability to indefinitely delay market entry by all other ANDA filers behind the Actavis bottleneck. Absent some inducement to abandon that posture, Zydus had every incentive to continue to litigate to a final judgment, launch a competitively priced, independent generic version of Rytary, and usher in competition from additional generics.

172. Rather than pursue its strong litigation position, Zydus agreed to dismiss its patent counterclaims and to forego independent entry into the Rytary market. In exchange, Zydus received an authorized generic license from Impax. By accepting this license, Zydus agreed to horizontally allocate markets with Impax: Zydus would market only the authorized generic version of Rytary (the brand's own product with different trade dress), while independent generic competition from Zydus's ANDA product, and from all other bottlenecked ANDA filers, was suppressed for Impax's and Zydus's joint benefit. Zydus launched as Impax's authorized generic partner in October 2025, years after competition should have begun.

173. Zydus's decision to abandon independent competition and accept the AG license caused independent harm to the Class even if, *arguendo*, the Impax-Actavis conduct was not unlawful. Even with the Impax-Actavis agreement in place, had Zydus pressed its litigation advantage to judgment (the likely outcome), Zydus could have launched a less expensive generic under its ANDA that would have competed on price against Rytary, and other generics, including AG Rytary, which Impax would have separately launched. Instead, as an authorized generic partner, Zydus entered the market on terms that served Impax's and Zydus's joint conspiratorial interests. Zydus thus agreed to suppress competition and preserve supracompetitive pricing at the expense of members of the Class.

174. Impax's, Actavis's, and/or Zydus's anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Rytary from generic competition. Impax's, Actavis's, and/or Zydus's actions allowed Impax to maintain a monopoly and

exclude competition in the market for Rytary and its AB-rated generic equivalents, effectively preserving the market solely for the benefit of Impax's monopoly profits, and for Actavis's and Zydus's benefit as generic sellers during artificially limited periods of competition.

175. Impax's, Actavis's, and/or Zydus's exclusionary conduct has delayed, prevented, and impeded the efficient sale of and competition from AB-rated generic Rytary in the United States and unlawfully enabled Impax and/or Zydus to sell Rytary without generic competition and thus, artificially inflated prices.

176. Impax's, Actavis's, and/or Zydus's anticompetitive conduct, which delayed the introduction into the U.S. marketplace of any AB-rated generic version of Rytary, caused Plaintiff and other members of the Class to pay more for their purchases of brand and generic Rytary from Defendants than they would have paid absent the misconduct alleged herein.

XI. ANTITRUST IMPACT

177. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Rytary and/or generic Rytary directly from Impax and/or Zydus. As a result of the unlawful anticompetitive conduct alleged herein, Plaintiff and other Class members were compelled to pay, and did pay, artificially inflated prices for Rytary and/or generic Rytary from Defendants. Those prices were substantially greater than the prices that Plaintiff and other Class members would have paid absent the illegal conduct alleged herein, because the prices of Rytary and generic Rytary were artificially inflated during the period of delay.

178. As a consequence, Plaintiff and other Class members have sustained and continue to sustain substantial losses and damage to their business and property in the form of overcharges on purchases from Defendants. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

* * *

XII. CLAIMS FOR RELIEF

COUNT I
VIOLATION OF 15 U.S.C. § 1
(AGAINST IMPAX)

179. Plaintiff hereby incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

180. Impax violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement with Actavis that restrained competition in the market for Rytary and its generic equivalents.

181. Plaintiff and other Class members have been injured in their business or property by the violation of 15 U.S.C. § 1. Plaintiff's and other Class members' injury consists of having paid higher prices for brand and/or generic Rytary from Defendants than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes the Defendants' conduct unlawful. Plaintiff and other Class members are direct purchasers and therefore the proper parties to bring a case concerning this conduct.

182. From the launch of Rytary in 2015 through at least October 2025, Impax possessed monopoly power in the relevant market. Absent Impax's wrongful conduct, as alleged herein, Impax should have lost its monopoly power well before October 2025.

183. In or about June 2018, Impax and Actavis entered into a reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Impax promised Actavis substantial consideration in exchange for Actavis's agreement to delay its launch of generic Rytary, the purpose and effect of which was to: (i) delay entry of generic Rytary in order to lengthen the period in which Impax's brand Rytary could monopolize the market and make supracompetitive profits; (ii) keep a competing generic off the market and allow Actavis to sell as the only generic Rytary during the first 80 days following Actavis's licensed entry date; (iii) reduce output and divide markets with respect to brand and generic Rytary; and (iv) maintain and/or raise the prices of brand and generic Rytary at supracompetitive levels during the period(s) affected by Impax's anticompetitive conduct and agreements.

184. There was and is no legitimate, non-pretextual, pro-competitive business justification for the reverse payment agreement that outweighs its harmful effect on competition and Plaintiff and other Class members. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

185. In addition, the agreement between Impax and Actavis was an illegal temporal horizontal market-allocation agreement, a *per se* violation of Section 1 of the Sherman Act. Actavis agreed not to compete with Impax from June 20, 2018 until July 31, 2025, and Impax agreed not to compete with Actavis from August 1, 2025 until October 20, 2025.

186. As a proximate and direct result of Impax's anticompetitive conduct and agreements, including the reverse payment, Plaintiff and other Class members incurred overcharge injury and damages on their purchases of brand and/or generic Rytary from Defendants.

COUNT II
VIOLATION OF 15 U.S.C. § 1
(AGAINST IMPAX AND ZYDUS)

187. Plaintiff hereby incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

188. Impax and Zydus violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Rytary and its generic equivalents.

189. Plaintiff and other Class members have been injured in their business or property by the violation of 15 U.S.C. § 1. Plaintiff's and other Class members' injury consists of having paid higher prices for brand and/or generic Rytary from Defendants than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes the Defendants' conduct unlawful. Plaintiff and other Class members are direct purchasers and therefore the proper parties to bring a case concerning this conduct.

190. From the launch of Rytary in 2015 through at least October 2025, Impax possessed monopoly power in the relevant market. Absent Defendants' wrongful conduct, as alleged herein, Impax should have lost its monopoly power well before October 2025.

191. In or about May 2020, Impax and Zydus entered into a reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Impax paid Zydus substantial consideration in exchange for Zydus's agreement to delay its generic Rytary launch and not trigger the forfeiture of Actavis's 180-day exclusivity, the purpose and effect of which was to: (i) delay entry of generic Rytary in order to lengthen the period in which Impax's brand Rytary could monopolize the market and make supracompetitive profits; (ii) keep a competing generic off the market and allow Zydus to sell as the only authorized generic Rytary during that period; (iii) reduce output and divide markets with respect to brand and generic Rytary; and (iv) maintain and/or raise the prices of brand and generic Rytary at supracompetitive levels during the period(s) affected by Defendants' anticompetitive conduct and agreements. These anticompetitive effects do not depend on whether the Impax-Actavis agreement is itself found unlawful, because absent the Impax-Zydus agreement, Zydus would have litigated the '608 patent to judgment, prevailed, and triggered forfeiture of Actavis's 180-day exclusivity, precipitating generic entry not only by Zydus's own ANDA generic Rytary product, but by other bottlenecked ANDA filers and an independent Impax AG, regardless of the propriety of the Impax-Actavis settlement.

192. Starting in October 2025, Impax shared monopoly profits with Zydus, and the arrangement enabled Impax to maintain an illegal monopoly.

193. There was and is no legitimate, non-pretextual, pro-competitive business justification for the reverse payment agreement that outweighs its harmful effect on competition and Plaintiff and other Class members. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

194. In addition, the agreement between Impax and Zydus was an illegal temporal horizontal market-allocation agreement, a *per se* violation of Section 1 of the Sherman Act. Zydus agreed not to compete with Impax from May 19, 2020 until October 20, 2025, and Impax agreed not to compete with Zydus from October 20, 2025 forward.

195. As a proximate and direct result of Defendants' anticompetitive conduct and agreements, including the reverse payment, Plaintiff and other Class members incurred overcharge injury and damages on their purchases of brand and/or generic Rytary from Defendants.

COUNT III
15 U.S.C. § 2 – MONOPOLIZATION/SCHEME TO MONOPOLIZE
(AGAINST IMPAX)

196. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

197. At all relevant times, Impax possessed monopoly power in the relevant market.

198. By its conduct as set forth above, Impax willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class thereby.

199. It was Impax's conscious object to further its dominance in the relevant market by and through its conduct set forth above.

200. Impax's conduct as set forth above constitutes an anticompetitive scheme to maintain monopoly power in the relevant market.

201. The scheme involved, *inter alia*, entering a reverse payment agreement or other unlawful arrangement to prevent Actavis from ushering in generic competition; erecting and maintaining a bottleneck preventing the FDA from granting final approval to manufacturers of generic Rytary; entering into a reverse payment agreement or other unlawful arrangement to prevent Zydus from breaking the bottleneck; and agreeing to restrict output and divide markets for brand and generic Rytary.

202. The goal, purpose, and/or effect of Impax's conduct was to maintain and extend its monopoly power with respect to Rytary and collect the unlawful profits derived therefrom. Impax's conduct to impair generic competition allowed Impax to continue charging supracompetitive prices for Rytary without a substantial loss of sales.

203. As a direct and proximate result of Impax's monopolistic conduct, as alleged herein, Plaintiff and the Class were harmed.

COUNT IV
15 U.S.C. § 2 – CONSPIRACY TO MONOPOLIZE
(AGAINST IMPAX AND ZYDUS)

204. Plaintiff hereby incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

205. Defendants conspired to unlawfully maintain Impax's monopoly power in the relevant market by agreeing and adhering to promises comprising a conspiracy to restrict output, divide markets, and/or fix prices with respect to Rytary and generic Rytary.

206. Defendants knowingly and intentionally entered into this conspiracy.

207. Defendants specifically intended that the conspiracy would maintain Impax's monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

208. Defendants each committed at least one overt act in furtherance of the conspiracy.

209. As a direct and proximate result of Defendants' concerted monopolistic conduct, as alleged herein, Plaintiff and the Class were harmed.

XIII. DEMAND FOR JUDGMENT

210. Plaintiff, on behalf of itself and the proposed Class, respectfully demands that this Court:

a) Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and declare the Plaintiff as the representative of the Class;

b) Enter joint and several judgments against the Defendants and in favor of the Plaintiff and the Class;

c) Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

d) Award the Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

e) Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIV. JURY DEMAND

211. Pursuant to Fed. R. Civ. P. 38, Plaintiff demands a trial by jury on all issues so triable.

Dated: July 27, 2026

Respectfully submitted,

By: /s/ *Kyla J. Gibboney*

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