IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SHIONOGI & CO., LTD., HOFFMANN-LA ROCHE INC., and GENENTECH INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 24-1264-MN
NORWICH PHARMACEUTICALS, INC., and ALVOGEN PB RESEARCH & DEVELOPMENT LLC,	)	
Defendants.	)	

DEFENDANTS NORWICH PHARMACEUTICALS, INC. AND ALVOGEN PB RESEARCH & DEVELOPMENT LLC'S
ANSWER AND COUNTERCLAIMS

Defendants Norwich Pharmaceuticals, Inc. ("Norwich") and Alvogen PB Research & Development LLC ("Alvogen") (collectively, "Defendants") hereby respond to the corresponding paragraphs of the Complaint of Plaintiffs Shionogi & Co., Ltd. ("Shionogi"), Hoffmann-La Roche Inc. ("HLR") and Genentech, Inc. ("Genentech") (collectively, "Plaintiffs") as follows:

NATURE OF THE ACTION

1. Paragraph 1 of the Complaint contains conclusions of law to which no response is required. To the extent an answer is required, Defendants admit that the Complaint purports to allege a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, that Plaintiffs allege is related to U.S. Patent No. 12,064,438 ("the '438 Patent"), and the pharmaceutical drug product XOFLUZA®. Defendants also admit that, through its regulatory agent Alvogen, Norwich submitted Abbreviated New Drug Application ("ANDA") No. 217449 to the United States Food and Drug Administration ("FDA"), seeking

approval to market 40 mg and 80 mg baloxavir marboxil tablets ("Norwich's ANDA Product") prior to the expiration of the '438 Patent. Except as otherwise admitted, the allegations are denied.

THE PARTIES

2. Defendants lack sufficient knowledge to admit or deny the allegations in Paragraph 2 of the Complaint, and therefore deny the same.

3. Defendants lack sufficient knowledge to admit or deny the allegations in Paragraph 3 of the Complaint, and therefore deny the same.

4. Defendants lack sufficient knowledge to admit or deny the allegations in Paragraph 4 of the Complaint, and therefore deny the same.

5. Admitted.

6. Admitted.

7. Defendants admit that Norwich and Alvogen are wholly owned by Alvogen Pharma US, Inc. To the extent Paragraph 7 contains allegations relating only to non-party Alvogen Pharma US, Inc., no response is required.

8. Defendants admit that the letter providing Notification Pursuant to Section 505(j)(2)(B)(iv), dated December 29, 2022 ("the First Notice Letter"), states that "Norwich has submitted to the United States Food and Drug Administration ('FDA'), and the FDA has received, Abbreviated New Drug Application No. 217449 ('the Norwich ANDA') under 21 U.S.C. § 355(j), which contains the required bioavailability or bioequivalence data or information to obtain approval to engage in the commercial manufacture, use, or sale of Baloxavir Marboxil Tablets, 40 mg and 80 mg ('the Norwich proposed ANDA products'). The Norwich ANDA identifies Xofluza (NDA No. 210854) as the Reference Listed Drug."

9. Defendants admit that the First Notice Letter was signed by the "Executive Director, Regulatory Affairs [for] Alvogen PB Research & Development LLC (Regulatory Agent for Norwich Pharmaceuticals, Inc.)." Defendants otherwise deny the remaining allegations of Paragraph 9.

10. Defendants admit that Norwich manufactures pharmaceutical products and that Alvogen is a regulatory agent for Norwich with respect to ANDA No. 217449. Defendants otherwise deny the remaining allegations of Paragraph 10.

11. Defendants admit that Alvogen is a regulatory agent for Norwich with respect to ANDA No. 217449. Defendants otherwise deny the remaining allegations of Paragraph 11.

12. Defendants admit that, through its regulatory agent Alvogen, Norwich submitted ANDA No. 217449 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import Norwich's ANDA Product in the United States prior to the expiration of the '438 Patent. Defendants otherwise deny the remaining allegations of Paragraph 12.

13. Norwich admits that it intends to commercially manufacture, use, offer for sale, sell and/or import Norwich's ANDA Product into the United States upon approval of ANDA No. 217449. Defendants otherwise deny the remaining allegations of Paragraph 13.

JURISDICTION AND VENUE

14. Paragraph 14 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants admit that the Complaint purports to allege an action for patent infringement under the patent laws of the United States, Title 35, United States Code. Defendants otherwise deny the remaining allegations of Paragraph 14.

15. Paragraph 15 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants do not contest that this Court has subject

matter jurisdiction over the claims asserted against Defendants for the limited purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 15.

16. Paragraph 16 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Norwich admits that it is organized and existing under the laws of Delaware. Norwich does not contest that this Court has personal jurisdiction over the claims asserted against Norwich for purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 16.

17. Paragraph 17 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Norwich admits that it did not contest that the United States District Court for the District of Delaware had personal jurisdiction over it for the limited purposes of the civil actions captioned by *Shionogi & Co., Ltd. et al. v. Norwich Pharms., Inc. et al.*, 23-161 (D. Del.), *Takeda Pharm. Co. Ltd. et al. v. Norwich Pharms., Inc.*, 20-953 (D. Del.), and *Salix Pharms., Ltd. et al. v. Norwich Pharms., Inc. et al.*, 20-430 (D. Del.). Norwich does not contest that this Court has personal jurisdiction over the claims asserted against Norwich for purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 17.

18. Paragraph 18 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Alvogen admits that it is organized and existing under the laws of Delaware. Alvogen does not contest that this Court has personal jurisdiction over the claims asserted against Alvogen for purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 18.

19. Paragraph 19 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Alvogen admits that it did not contest that the

United States District Court for the District of Delaware had personal jurisdiction over it for the limited purposes of the civil actions captioned by *Shionogi & Co., Ltd. et al. v. Norwich Pharms., Inc. et al.*, 23-161 (D. Del.), *Salix Pharms., Ltd. et al. v. Norwich Pharms., Inc. et al.*, 20-430 (D. Del.), and *BioDelivery Sciences International, Inc. et al. v. Alvogen PB Research & Development LLC et al.*, 18-1395 (D. Del.). Alvogen does not contest that this Court has personal jurisdiction over the claims asserted against Alvogen for purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 19.

20. Paragraph 20 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants do not contest that this Court has personal jurisdiction over the claims asserted against Defendants for purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 20.

21. Paragraph 21 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Defendants do not contest that this Court has personal jurisdiction over the claims asserted against Defendants for purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 21.

22. Paragraph 22 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Norwich does not contest that venue is proper in this Court for the limited purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 22.

23. Paragraph 23 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Alvogen does not contest that venue is proper in this Court for the limited purposes of this action only. Defendants otherwise deny the remaining allegations of Paragraph 23.

THE ’438 Patent

24. Defendants lack sufficient knowledge to admit or deny the allegations in Paragraph 24 of the Complaint, and therefore deny the same.

25. Defendants lack sufficient knowledge to admit or deny the allegations in Paragraph 25 of the Complaint, and therefore deny the same.

26. Defendants lack sufficient knowledge to admit or deny the allegations in Paragraph 26 of the Complaint, and therefore deny the same.

27. Paragraph 27 contains conclusions of law to which no response is required. To the extent a response is required, Defendants admit that Exhibit A to the Complaint purports to be a copy of the ’438 Patent, has an issue date of August 20, 2024 on its face, and bears the title “Pharmaceutical Preparation Excellent in Light Stability and Dissolution Property.” Defendants lack sufficient knowledge to admit or deny the remaining allegations in Paragraph 27 of the Complaint and therefore deny the same.

FACTUAL BACKGROUND

XOFLUZA® (baloxavir marboxil)

28. Defendants admit that XOFLUZA® (baloxavir marboxil) is currently indicated for “[t]reatment of acute uncomplicated influenza in patients 5 years of age and older who have been symptomatic for no more than 48 hours and who are otherwise healthy or are at high-risk of developing influenza-related complications” and “[p]ost-exposure prophylaxis of influenza in patients 5 years of age and older following contact with an individual who has influenza.” Defendants also admit that the XOFLUZA® label states that XOFLUZA® (baloxavir marboxil) is an influenza virus polymerase acidic (PA) endonuclease inhibitor. Defendants deny the remaining allegations in Paragraph 28 of the Complaint.

29. Defendants admit that FDA's website lists Genentech as the applicant for New Drug Application ("NDA") No. 210854 for XOFLUZA® (baloxavir marboxil) tablets, for oral use. Defendants lack sufficient knowledge to admit or deny the remaining allegations in Paragraph 29 of the Complaint and therefore deny the same.

30. Defendants admit that the electronic version of the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") lists the '438 Patent for NDA No. 210854. Defendants lack sufficient knowledge to admit or deny the remaining allegations in Paragraph 30 of the Complaint and therefore deny the same.

Defendants' ANDA No. 217449

31. Paragraph 31 contains conclusions of law to which no response is required. To the extent a response is required, Defendants admit that the First Notice Letter states that, through its regulatory agent, Norwich submitted ANDA No. 217449 to FDA seeking approval to commercially manufacture and sell Norwich's ANDA Product in the United States prior to expiration of U.S. Patent Nos. 8,927,710 ("the '710 Patent"), 8,987,441 ("the '441 Patent"), 9,815,835 ("the '835 Patent"), 10,392,406 ("the '406 Patent"), 10,633,397 ("the '397 Patent"), 10,759,814 ("the '814 Patent"), 11,261,198 ("the '198 Patent"), and 11,306,106 ("the '106 Patent"). Defendants lack sufficient knowledge to admit or deny the remaining allegations in Paragraph 31 of the Complaint and therefore deny the same.

32. The '438 Patent was listed in the Orange Book after Norwich, through Alvogen, submitted ANDA No. 217449 and after Norwich sent, by and through Alvogen, the First Notice Letter dated December 29, 2022. On January 29, 2025, Norwich sent, by and through Alvogen, a letter to Plaintiffs Shionogi and Genentech providing Notification Pursuant to Section 505(j)(2)(B)(iv) for the '438 Patent ("the Second Notice Letter"). Defendants lack sufficient

knowledge to admit or deny the remaining allegations in Paragraph 32 of the Complaint and therefore deny the same.

33. Paragraph 33 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 33.

34. Paragraph 34 contains conclusions of law to which no response is required. To the extent a response is required, Defendants admit that ANDA No. 217449 references NDA No. 210854 and Xofluza (baloxavir marboxil) as the reference listed drug. Defendants also admit that ANDA No. 217449 contains data demonstrating that Norwich's ANDA Product is bioequivalent to the reference listed drug. Defendants deny the remainder of the allegations of Paragraph 34.

35. Paragraph 35 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 35.

36. Admitted.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 12,064,438

37. Defendants restate and incorporate by reference their responses to the allegations of Paragraphs 1–36 as though fully set forth herein.

38. Paragraph 38 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 38.

39. Paragraph 39 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 39.

40. Denied.

41. Paragraph 41 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 41.

42. Paragraph 42 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 42.

PRAYER FOR RELIEF

WHEREFORE, Defendants deny that Plaintiffs are entitled to any of the relief requested in the "Prayer for Relief" or otherwise stated in the Complaint.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer or to their ability to seek and allege any defenses not presently known or that are revealed during the course of discovery, Defendants assert the following affirmative defenses in response to the Complaint:

First Affirmative Defense

Each claim of the '438 Patent that Plaintiffs assert against Defendants is invalid for failing to comply with one or more provision of Title 35 of the United States Code, including §§ 101, 102, 103, 112, any of the equitable defenses, and/or the judicial doctrine barring double-patenting.

Second Affirmative Defense

Defendants have not infringed and are not infringing any valid and enforceable claim of the '438 Patent under 35 U.S.C. § 271(e) by the submission of ANDA No. 217449.

Third Affirmative Defense

Defendants have not infringed, are not infringing, and will not infringe, either directly or by contribution or inducement, literally or by doctrine of equivalents, any valid and enforceable claim of the '438 Patent under 35 U.S.C. § 271(a), (b), (c), or (g).

Fourth Affirmative Defense

The Complaint fails to state a claim upon which relief may be granted under 35 U.S.C. § 271(a), (b), (c), or (g).

Fifth Affirmative Defense

The Complaint fails to state a claim upon which relief may be granted under 35 U.S.C. § 271(a), (b), (c), (e), or (g). For example, Alvogen did not "submit" Norwich Pharmaceuticals, Inc.'s ANDA No. 217449 as required by 35 U.S.C. § 271(e)(2). *See Adverio Pharma GmbH v. Alembic Pharms. Ltd.*, C.A. No. 18-cv-73-LPS, 2019 WL 581618 (D. Del. Feb. 13, 2019). Alvogen is the authorized regulatory agent for Norwich's ANDA No. 217449. Alvogen will not engage in the commercial manufacture, use, or sale of Norwich's ANDA Product after FDA approves ANDA No. 217449. Accordingly, the Complaint fails to state a plausible claim of patent infringement against Alvogen at least because it fails to allege sufficient facts that establish Alvogen's commercial involvement with Norwich's ANDA Product after FDA approves Norwich Pharmaceutical, Inc.'s ANDA No. 217449.

Sixth Affirmative Defense

This Court lacks subject matter jurisdiction over any and all claims against Alvogen arising under 35 U.S.C. § 271(a), (b), (c), (e), or (g).

COUNTERCLAIMS

For their counterclaims against Plaintiffs Shionogi & Co. ("Shionogi"), Hoffmann-La Roche Inc. ("HLR"), and Genentech, Inc. ("Genentech") (collectively, "Plaintiffs"), Defendants Norwich Pharmaceuticals, Inc. ("Norwich") and Alvogen PB Research & Development LLC ("Alvogen") (collectively, "Defendants") allege upon knowledge with respect to their own acts, and upon information and belief as to other matters, as follows:

THE PARTIES

1. Norwich is a corporation organized and existing under the laws of the State of Delaware having its corporate offices and principal place of business at 6826 Highway 12, Norwich, New York 13815.

2. Alvogen is a limited liability company organized and existing under the laws of Delaware having its corporate offices and principal place of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058.

3. On information and belief, Shionogi is a corporation organized and existing under the laws of Japan, having a principal place of business in Osaka, Japan.

4. On information and belief, HLR is a corporation organized and existing under the laws of New Jersey, having a principal place of business in Little Falls, New Jersey.

5. On information and belief, Genentech is a corporation organized and existing under the laws of Delaware, having a principal place of business in South San Francisco, California.

JURISDICTION AND VENUE

6. Defendants reallege Paragraphs 1–5 of the Counterclaims as though fully set forth herein.

7. These are counterclaims for declaratory judgment of non-infringement and/or invalidity of one or more claims of United States Patent No. 12,064,438 ("the '438 Patent") pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the Patent Laws of the United States, 35 U.S.C. § 1, et seq., 25 U.S.C. §271(e)(5), and 21 U.S.C. § 355(j) for the purpose of determining an actual and justiciable controversy between the parties.

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over the Plaintiffs because Plaintiffs have submitted to the personal jurisdiction of this Court.

10. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400 because Plaintiffs have submitted to the jurisdiction of this Court.

ACTS GIVING RISE TO THE ACTION

11. Defendants reallege Paragraphs 1–10 of the Counterclaims as though fully set forth herein.

12. In the Complaint, Plaintiffs allege that Shionogi is the assignee of the '438 Patent, and that HLR is an exclusive licensee and Genentech is the exclusive sublicensee of the '438 Patent.

13. In the Complaint, Plaintiffs allege that Genentech holds approved NDA No. 210854 for XOFLUZA® (baloxavir marboxil) tablets, for oral use.

14. On its face, the '438 Patent, attached as Exhibit A to the Complaint, contains the title "Pharmaceutical Preparation Excellent in Light Stability and Dissolution Property," and states that the '438 Patent issued on August 20, 2024.

15. On information and belief, Genentech caused the '438 Patent to be listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for XOFLUZA®.

16. On behalf of Norwich, Alvogen submitted ANDA No. 217449 in order to obtain approval to engage in the commercial manufacture, use, or sale of 40 mg and 80 mg baloxavir marboxil tablets ("Norwich's ANDA Product") in the United States.

17. On January 29, 2025, Norwich sent, by and through Alvogen, the Second Notice Letter to Plaintiffs Shionogi and Genentech notifying Plaintiffs that Norwich amended ANDA

No. 217449 to include a patent certification ("Paragraph IV certification") that the '438 Patent is invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of Norwich's ANDA Product. The Second Notice Letter included a detailed statement of the factual and legal bases for the Paragraph IV certification and an Offer of Confidential Access to Norwich's ANDA No. 217449.

CASE OR CONTROVERSY

18. Defendants reallege Paragraphs 1–17 of the Counterclaims as though fully set forth herein.

19. By maintaining the listing of the '438 Patent in the Orange Book, Plaintiffs represent that the '438 Patent claim the approved drug XOFLUZA®, or a method of using that drug, and that a claim for patent infringement "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

20. On November 18, 2024, Plaintiffs filed a Complaint alleging, *inter alia*, the infringement of the '438 Patent against Defendants.

21. The submission of ANDA No. 217449 to FDA creates the necessary case or controversy and subject matter jurisdiction for Plaintiffs to sue Defendants—and for Defendants to obtain a declaratory judgment against Plaintiffs—regarding infringement of the '438 Patent.

22. An actual and justiciable controversy exists between Defendants and Plaintiffs relating to the '438 Patent.

23. A declaration of rights between the parties is both appropriate and necessary to establish that Defendants will not infringe any valid and/or enforceable claim of the '438 Patent.

COUNT I: DECLARATION OF NONINFRINGEMENT OF THE '438 PATENT

24. Defendants reallege Paragraphs 1–23 of the Counterclaims as though fully set forth herein.

25. The submission of ANDA No. 217449 to FDA does not directly infringe or infringe through inducement or contribution, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '438 Patent.

26. The commercial manufacture, use, sale, offer for sale, and/or importation of Norwich's ANDA Product does not and will not directly infringe or infringe through inducement or contribution, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '438 Patent.

27. An actual and justiciable controversy exists between Defendants and Plaintiffs regarding the noninfringement of the '438 Patent.

28. Defendants are entitled to a declaration that the submission of ANDA No. 217449 to FDA does not infringe any valid and enforceable claim of the '438 Patent.

29. Defendants are entitled to a declaration that the commercial manufacture, use, sale, offer for sale and/or importation of Norwich's ANDA Product does not and will not infringe any valid and enforceable claim of the '438 Patent.

COUNT II: DECLARATION OF INVALIDITY OF '438 PATENT

30. Defendants reallege paragraphs 1–29 of the Counterclaims as though fully set forth herein.

31. The claims of the '438 Patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or the judicial doctrine barring double-patenting.

32. For example, the prior art publications including but not limited to WIPO Patent App. Pub. No. 2016/175224 to Kawai et al. (published Nov. 3, 2016) ("Kawai WO '224 Publication"), WIPO Patent App. Pub. No. 2014/197660 A1 to Conca et al. (published Dec. 11, 2014) ("Conca WO '660 Publication"), U.S. Patent No. 4,543,370 to Porter et al. (issued Sept. 24, 1985) ("the '370 Patent"), Howard C. Ansel et al., *Dosage Form Design: Pharmaceutic and Formulation Considerations*, *in Pharmaceutical Dosage Forms and Drug Delivery Systems* (7th ed. 1999) ("Ansel 1999"), *Handbook of Pharmaceutical Excipients* (Raymond C. Rowe, Paul J. Sheskey, & Siân C. Owen eds., 5th ed. 2006) ("Handbook of Pharmaceutical Excipients 2006"), and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, *ICH Harmonised Tripartite Guideline; Stability Testing of New Drug Substances and Products Q1B* (1999) ("Q1B Guideline 1996") render anticipated and/or obvious, alone or in combination with one or more prior art publications and common knowledge, each of the claims of the '438 Patent.

33. In addition, claims of the '438 Patent fail to comply with the requirements of 35 U.S.C. § 112, including, for example, the written description and/or enablement requirements.

34. An actual and justiciable controversy exists between Defendants and Plaintiffs regarding the validity of the '438 Patent.

35. Defendants are entitled to a declaration that the claims of the '438 Patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully request this Court to enter judgment for Defendants as follows:

A. That the Complaint be dismissed with prejudice, and that Plaintiffs take nothing by their Complaint;

B. That Defendants do not and will not infringe any valid and enforceable claim of the ’438 Patent;

C. Declaring that the manufacture, use, offer for sale, sale, and importation of Norwich’s ANDA Product does not and will not infringe any valid and enforceable claim of the ’438 Patent;

D. Declaring that the Submission of ANDA No. 217449 by Alvogen on behalf of Norwich does not infringe any valid and enforceable claim of the ’438 Patent;

E. Declaring that the claims of the ’438 Patent are invalid;

F. Declaring that this is an exceptional case under 35 U.S.C. § 285;

G. Awarding Defendants their costs, expenses, and attorneys’ fees pursuant to 35 U.S.C. § 285, other applicable statutes or rules, or the general power of the Court;

H. Preliminarily and permanently enjoining the Plaintiffs, their officers, agents, servants, employees, attorneys, successors, and any person who acts in concert or participation with Plaintiffs from using the ’438 Patent to block, hamper, hinder, or obstruct FDA approval of the products described in ANDA No. 217449; and

I. Awarding to Defendants such further relief as this Court may deem necessary, just, and proper.

/s/ Nathan R. Hoeschen

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