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IN THE UNITED STATES BANKRUPTCY COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

In re: EIGER BIOPHARMACEUTICALS, INC., *et al.* Debtors.	Chapter 11 Case No. 24-80040 (SGJ) (Jointly Administered)

REPLY IN SUPPORT OF MOTION FOR ALLOWANCE OF ADMINISTRATIVE EXPENSE CLAIM OF SENTYNL THERAPEUTICS, INC.

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Cases

Rules and Regulations

Sentynl Therapeutics, Inc. ("Sentynl"), submits this reply (the "Reply") in support of its *Motion for Allowance of Administrative Expense Claim* (the "Motion for Allowance")[1] and respectfully states as follows:

PRELIMINARY STATEMENT

1. Zokinvy® (non-proprietary name, "lonafarnib"), is a ***commercial*** drug and the only treatment for Hutchinson-Gilford Progeria Syndrome (HGPS) and processing deficient Progeroid Laminopathies (collectively, "Progeria"), which are ultra-rare, fatal, pediatric genetic diseases.[2] [redacted]

2. EIT[6] and the LT argue, for their side, that Corden and Lonza also manufacture lonafarnib for non-commercial ***investigational*** uses. One such unapproved, investigational use is

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1 Docket No. 729. Capitalized terms used but not defined herein have the meanings ascribed to such terms in the Motion for Allowance.

2 Zokinvy® (lonafarnib) is approved in the U.S., Europe, and Japan, and provided to Progeria patients around the world through compassionate use and managed access programs. *See, e.g.,* Zokinvy® approved FDA labeling (https://www.dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=956a142f-35d6-4fe3-8aef-7e4878d275ed).

3 *See* **Exhibit A** (flowchart of Zokinvy supply chain).

4 [redacted]

5 Dundon Advisers LLC, in its capacity as liquidating trustee (the "LT" or "Liquidating Trustee").

6 EIT Pharma, Inc. (f/k/a Eiger InnoTherapeutics, Inc.) ("EIT").

for the *potential* treatment of HDV. HDV patients have other treatment options, one product is already on the market in Europe.[7] EIT might never obtain regulatory approval to sell its lonafarnib for HDV product commercially, and it might be less effective than existing HDV treatments.

3. [redacted]

4. [redacted]

7 Hepcludex® (Bulevirtide). *See* https://www.ema.europa.eu/en/medicines/human/EPAR/hepcludex .

8 [redacted]

9 Gary Broadbent, in his capacity as the Plan Administrator appointed pursuant to the Fifth Amended Joint Plan of Liquidation of Eiger Biopharmaceuticals, Inc. and its Debtor Affiliates (the "PA" or "Plan Administrator").

[redacted]

5. [redacted]

[redacted]

6. [redacted]

[redacted]

7. [redacted]

[redacted]

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10 [redacted]

11 [redacted]

12 [redacted]

13 *Sentynl's Motion (I) to Enforce the Zokinvy Sale Order and (II) for Contempt Against Eiger InnoTherapeutics, Inc.* [Docket Nos. 779, 781] ("Motion to Enforce").

14 **Exhibit C**.

15 *See* **Exhibit D** [redacted]

[redacted]

8. [redacted]

9. [redacted]

[16] The Motion for Allowance raised several breaches. Some are not issues today. One, the IQVIA issue is, by and large, resolved. Though Sentynl has yet to receive the global safety database, which is itself a significant regulatory concern, EIT has stated to Sentynl that it has signed Change Orders that direct IQVIA to transfer the database. Sentynl will seek legal fees and expenses in connection with the IQVIA-related portion of its administrative expense. Two, the Zokinvy® repayment liability to France is not at issue in this contested matter. The estate reserved about $3 million to pay Sentynl pre-closing costs because the French government seeks a refund of €2,900,225. Sentynl is still negotiating with France. Meanwhile, the estate must continue to reserve the reimbursement funds.

[17] [redacted]

[redacted]

10. [redacted]

[redacted]

11. [redacted]

[redacted]

[18] *See* **Exhibit E** [redacted]

[19] [redacted]

[20] *See* **Exhibit F** [redacted]

12.

13.

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24

25

[redacted]

14. [redacted]

[redacted]

15. [redacted]

[redacted]

16. [redacted]

[redacted]

[redacted]

17. [redacted]

18. [redacted]

DETAILS OF THE SUPPLY CHAIN

A. Commercial Drug Manufacturing Overview

19. Zokinvy® is a *commercial* drug and the only approved treatment for Progeria, a group of ultra-rare, fatal, pediatric genetic diseases. Lonafarnib, the active ingredient in

[26] *Declaration of David Apelian in Support of the Chapter 11 Petitions and First Day Pleadings* [Docket No. 19 ¶ 7].

[27] *Objection and Response of the Liquidating Trustee and Plan Administrator to Motion for Allowance of Administrative Expense Claim of Sentynl Therapeutics, Inc.* [Docket No. 777] (the "Objection").

[28] *See* Objection ¶ 1.

Zokinvy®, has been studied for decades in other potential applications. One such application is an investigational treatment of the communicable disease HDV, a potentially larger market (depending on the infection rate), but for which alternative treatments are already either: (a) in advanced clinical trials; or (b) already commercially available in Europe. [redacted]

20. Drugs in the market require compliance with Good Manufacturing Practice ("GMP") requirements, under regulations promulgated worldwide, especially the U.S. All commercial drug manufacturing *must* be performed in *full* compliance of GMP requirements. The requirements are set by the FDA and similar regulatory authorities around the world; they are not

[redacted]

a liability management practice. For example, in the U.S., GMP requirements for production, packaging, and storage of commercial drugs are found in 21 C.F.R. §§ 210-211.

21. NDA/MAH holders frequently partner with CDMOs to produce drugs at scale. CDMOs have infrastructure, equipment, and expertise for raw material sourcing, formulation, packaging, and distribution, ensuring compliance with regulatory standards, and maintaining the quality of the final product. [redacted]

B. [redacted]

22. [redacted]

[30] *See* **Exhibit A**.

[redacted]

C. [redacted]

23. [redacted]

Sentynl requests that the Court take judicial notice of the following restrictive regulations:

a. 21 C.F.R. § 211.25(b), and how it provides for every person responsible for supervising the manufacture, processing, packing, or holding of a drug product to have education, training, and experience to perform its functions to provide assurance that the drug product has the requisite safety, identity, strength, quality, and purity.

b. 21 C.F.R. § 211.34, and how it provides similar education and training requirements for consultants advising on the manufacturing process.

24. [redacted]

25. [redacted]

[31] [redacted]

[redacted] The FDA has explained that a pharmaceutical quality system should include appropriate processes, resources, and responsibilities to provide assurance of the quality of any outsourced activities.[32] [redacted]

26. FDA guidance illustrates the agency's expectation that the drug manufacturing process is handled only by the NDA owner and the CDMO.[33] [redacted] "When an owner uses a contract facility, the *owner's quality unit is legally responsible* for approving or rejecting drug products manufactured by the contract facility."[34] Further, "the *owners' quality units are ultimately responsible* for ensuring that the products are manufactured in accordance with CGMP."[35] [redacted] Moreover, involving additional parties in the manufacturing

[32] *See* U.S. FOOD & DRUG ADMIN., Q10 PHARMACEUTICAL QUALITY SYSTEM: GUIDANCE FOR INDUSTRY (2009), https://www.fda.gov/media/71553/download. This includes assessing the "suitability and competence of potential contractors before outsourcing operations," and documenting all activities and requirements in a written agreement. *Id.* at 8.

[33] *See* U.S. FOOD & DRUG ADMIN., CONTRACT MANUFACTURING ARRANGEMENTS FOR DRUGS: QUALITY AGREEMENTS: GUIDANCE FOR INDUSTRY (2016), https://www.fda.gov/media/86193/download. This guidance also uses the term "both parties" to refer to all parties to a quality agreement, reflecting FDA's expectation that quality agreements are between an NDA owner and CDMO, and not any other third party. *Id.* at 6, 9, 10.

[34] *Id.* at 4 (emphasis added).

[35] *Id.* at 5 (emphasis added). "CGMP" means Current Good Manufacturing Practice.

[36] *Id.* at 6.

process can create hindering interdependencies and increase risk of noncompliance.[37]

27. [redacted]

D. [redacted]

28. [redacted]

[37] "While manufacturing and supply chain diversity can be enablers of product availability, increasingly complex supply chains lead to interdependencies that can introduce systemic quality/manufacturing risks impacting supply chain robustness." U.S. FOOD & DRUG ADMIN., Q9(R1) QUALITY RISK MANAGEMENT: GUIDANCE FOR INDUSTRY (2023), https://www.fda.gov/media/167721/download.

[38] *See* **Exhibit H** [redacted]

[redacted]

29. [redacted]

[redacted]

[redacted]

30. [redacted]

31. [redacted]

E. [redacted]

32. [redacted]

[39] *See* **Exhibit I** [redacted]

FURTHER REPLY IN SUPPORT OF MOTION FOR ALLOWANCE

A. [redacted]

33. [redacted]

34. Commercial drugs must be manufactured by GMP compliant facilities. Non-compliance means the drug cannot be released to the public. [redacted]

35. [redacted]

36. [redacted]

[redacted]

[redacted]

37. [redacted]

[redacted]

38. [redacted]

[redacted]

40 **Exhibit F** (emphasis added).

41 *See* **Exhibit J** [redacted]

[redacted]

B. [redacted]

39. [redacted]

40. [redacted]

[42] [redacted]

[43] *See* **Exhibit K** [redacted]

[44] [redacted]

C. [redacted].

41. [redacted]

42. [redacted]

43. [redacted]

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45 *See Response of the Liquidating Trustee to Emergency Motion of Sentynl Therapeutics, Inc. for Entry of an Order (I) Setting Status Conference and Continuing Evidentiary Hearing; (II) Authorizing Additional Pages for Sentynl's Reply Brief in Support of It* [Docket No. 799] (the "LT's Response to Sentynl's Emergency Motion") at ¶¶ 4, 13-16.

46 Section 2.1(a) of the Sublicense Agreement.

47 "A court's fundamental objective in interpreting a contract is to determine the parties' intent from the language employed and to fulfill their reasonable expectations." *Landmark Ventures, Inc. v. H5 Techs., Inc.*, 58 N.Y.S.3d 591 (N.Y. Sup. Ct. A.D. 2017).

[redacted].

44. [redacted]

CONCLUSION

[redacted]

Sentynl requests the Court hold an evidentiary hearing and, upon presentation of evidence of a breach by the LT and damages that the Court allow Sentynl's administrative expense against the estate as shown at trial and such other and further relief as is just and necessary.

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48 [redacted]

49 LT's Response to Sentynl's Emergency Motion ¶ 4.

50 [redacted]

Dated: April 7, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on April 7, 2025, I caused a copy of the foregoing Motion to be served by the Electronic Case Filing System for the United States Bankruptcy Court for the Northern District of Texas and an unredacted copy to be emailed to the following parties.

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