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IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LEAH R. SMITH and AKIDA MORGAN, *Plaintiffs,* v. **LUITPOLD PHARMACEUTICALS, INC., AMERICAN REGENT, INC., DAIICHI SANKYO, INC., DAIICHI SANKYO US HOLDINGS, INC., VIFOR PHARMA LTD., VIFOR PHARMA PARTICIPATIONS LTD., VIFOR (INTERNATIONAL) AG,** and **RELYPSA INC.,** *Defendants.*	EASTERN DISTRICT OF PENNSYLVANIA PHILADELPHIA DIVISION CIVIL ACTION NO. 2:21-cv-00601-WB Civil Action *Filed Electronically* **COMPLAINT** **AND JURY DEMAND**

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Plaintiffs Leah R. Smith and Akida Morgan, by and through their undersigned counsel, bring this civil action against the above-named Defendants for personal injuries and damages, and allege as follows:

PARTIES

1. Plaintiffs Leah R. Smith and Akida Morgan reside in Robertsdale, Alabama. Plaintiffs Smith and Morgan are married. Plaintiff Smith suffered serious physical injuries and economic damages due to her use of the injectable iron product, Injectafer (ferric carboxymaltose).

The American Regent Defendants

2. Defendant Luitpold Pharmaceuticals, Inc. ("Luitpold") was a New York corporation. At all relevant times, Luitpold maintained its principal offices in Norristown, Pennsylvania and Shirley, New York and was registered to do business throughout Pennsylvania, including within the county of Philadelphia. Luitpold was the parent to its subsidiary, American Regent, Inc.

3. At all relevant times, and within Pennsylvania, Luitpold engaged in the business of researching, developing, designing, testing, licensing, manufacturing, distributing, supplying, selling, labeling, promoting, marketing, and/or introducing into commerce the Injectafer product. Luitpold was the Sponsor of the New Drug Application ("NDA") submitted to the FDA on Injectafer in 2013.

4. Defendant American Regent, Inc. ("American Regent") is a New York corporation. At all relevant times, American Regent had a principal place of business at in Shirley, New York, sharing an office with Luitpold. Upon information and belief, American Regent also operates out of its Norristown, Pennsylvania office and is registered to do business in

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Pennsylvania. American Regent was a subsidiary of Luitpold until approximately December 31, 2008.

5. Upon information and belief, on or about December 31, 2008, Luitpold merged American Regent into itself, and the surviving entity – Luitpold – was renamed American Regent.[1] The new entity of American Regent is a wholly owned subsidiary of Daiichi Sankyo, Inc.

6. At all relevant times, and within Pennsylvania, American Regent has engaged in the business of researching, developing, designing, testing, licensing, manufacturing, distributing, supplying, selling, labeling, promoting, marketing, and/or introducing into commerce the Injectafer product.

7. Luitpold was the primary holder of a license to manufacture and market Injectafer from Vifor (International) Inc. until the merger. American Regent is the manufacturer currently listed on the Injectafer label, still under license from Vifor (International) Inc.

8. Upon information and belief, both American Regent and Luitpold were and are part of the Daiichi Sankyo Group.

The Daiichi Sankyo Defendants

9. Defendant Daiichi Sankyo, Inc. ("DSI") is a Delaware corporation with its principal place of business in Basking Ridge, New Jersey. DSI is the United States subsidiary of Daiichi Sankyo Co., Ltd. ("DSC"), located in Tokyo, Japan, and is a member of the Daiichi Sankyo Group. DSI is wholly owned by Defendant Daiichi Sankyo U.S. Holdings, Inc.

10. Defendant Daiichi Sankyo U.S. Holdings, Inc. ("DS Holdings") is a Delaware

[1] Since the merger between Luitpold and American Regent resulted in an entity called American Regent, any allegation throughout the Complaint specific to Luitpold also applies to its successor, American Regent.

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corporation with its principal place of business in Basking Ridge, New Jersey. DS Holdings wholly owns DSI. Upon information and belief, DS Holdings is also a subsidiary of DSC and is a member of the Daiichi Sankyo Group.

11. Upon information and belief, DSI is or was also known as Sankyo USA Development, Sankyo Pharma Development, Sankyo Pharma, Inc., Daiichi Sankyo Group, and Daiichi Pharma Holdings, Inc. Upon information and belief, DSI operates as the U.S. headquarters of DSC.

12. At all relevant times, DSI is and was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, and selling the Injectafer product. Starting in or around January 2017, DSI assumed the role of promoting and marketing Injectafer in the United States.

13. Upon information and belief, at all relevant times, DSI exercised control over the DSI subsidiaries, Luitpold and American Regent, with control over all relevant decisions, policies, and conduct regarding the research, development, design, licensing, manufacture, distribution, marketing, promotion, and selling of Injectafer.

14. Upon information and belief, DS Holdings is and was at all times engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, and selling the Injectafer product.

15. Upon information and belief, DS Holdings exercised ultimate control, and was responsible for the actions and omissions of its wholly owned subsidiary, DSI.

16. Upon information and belief, there existed at all relevant times a unity of interest in ownership between DS Holdings and DSI such that independence from, or separation between, these two Defendants does not and has never existed. Each of them is an alter ego of the other.

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17. Because of the unity of operations and ownership, DSI and DS Holdings are hereinafter referred to as the "Daiichi Sankyo Defendants."

The Vifor Defendants

18. Defendant Vifor Pharma Ltd. ("Vifor Pharma") is a for-profit corporation headquartered, organized, and existing under the laws of Switzerland, with an office location at Rechenstrasse 37 CH-9014 St. Gallen.

19. Defendant Vifor Pharma Participations Ltd. ("Vifor Participations") is a for-profit corporation headquartered, organized, and existing under the laws of Switzerland, with an office location at Rechenstrasse 37 CH-9014 St. Gallen. Vifor Participations is a wholly owned subsidiary of Vifor Pharma.

20. Defendant Vifor (International) AG a/k/a Vifor (International) Inc. ("Vifor International") is a for-profit corporation headquartered in Switzerland with an office location at Rechenstrasse 37 CH-9014 St. Gallen. Vifor International is a wholly owned subsidiary of Vifor Participations, Ltd.

21. Defendant Relypsa Inc. ("Relypsa") is Delaware corporation with its principal office in Redwood City, California. Relypsa Inc. is a wholly owned subsidiary of Vifor Pharma, and a United States Corporate Affiliate of Vifor International.

22. Because of the unity of operations and ownership, Vifor Pharma, Vifor Participations, Vifor International, and Relypsa are hereinafter referred to as the "Vifor Defendants" or "Vifor."

23. The Vifor Defendants are in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into commerce ferric carboxymaltose, or its European brand bioequivalent, Ferinject.

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