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18 *Attorneys for Plaintiffs Amarin Pharma, Inc.  
and Amarin Pharmaceuticals Ireland Limited*

19 **UNITED STATES DISTRICT COURT**  
20 **DISTRICT OF NEVADA**

21 AMARIN PHARMA, INC. and AMARIN  
22 PHARMACEUTICALS IRELAND LIMITED,

23 Plaintiffs,

24 v.

25 HIKMA PHARMACEUTICALS USA INC.,  
26 *et al.*,

27 Defendants.

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Chelsea Latino (Nev. Bar No. 14227)  
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CASE NO.: 2:16-cv-02525-MMD-NJK

(Consolidated with  
2:16-cv-02562-MMD-NJK)

**JOINT STIPULATIONS OF FACT**

1 **I. INTRODUCTION**

2 1. This is a civil action for patent infringement arising under the patent laws  
3 of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271(e)(2), and the  
4 Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, arising from Defendants’<sup>1</sup> filing of  
5 Abbreviated New Drug Applications (“ANDAs”) under Section 505(j) of the Federal Food,  
6 Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(j), seeking approval from the United States  
7 Food and Drug Administration (“FDA”) to market generic versions of Plaintiffs’<sup>2</sup> VASCEPA<sup>®</sup>  
8 product.

9 **II. STIPULATED FACTS**

10 For purposes of this case only, the parties stipulate to the following facts, which require  
11 no proof at trial:

12 **A. THE PARTIES**

13 2. Plaintiff Amarin Pharma, Inc. is a company organized and existing under  
14 the laws of Delaware with its principal place of business at 440 Route 22, Bridgewater, NJ  
15 08807.

16 3. Plaintiff Amarin Pharmaceuticals Ireland Limited is a company  
17 incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2,  
18 Dublin, Ireland.

19 4. Defendant Hikma Pharmaceuticals USA Inc. is a company organized and  
20 existing under the laws of Delaware with its principal place of business at 246 Industrial Way  
21 West, Eatontown, NJ 07724.

22  
23  
24 <sup>1</sup> Defendants Hikma Pharmaceuticals USA Inc. and Hikma Pharmaceuticals International  
25 Limited (collectively, “Hikma”) and Defendants Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s  
Laboratories, Ltd. (collectively, “DRL”) (Hikma and DRL collectively, “Defendants”).

26 <sup>2</sup> Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited  
27 (collectively, “Plaintiffs” or “Amarin”).

1           5. Defendant Hikma Pharmaceuticals International Limited is a company  
2 incorporated under the laws of the United Kingdom with registered offices at 1 New Burlington  
3 Place, London, England W1S 2HR.

4           6. Defendant Dr. Reddy's Laboratories, Inc. is a company organized and  
5 existing under the laws of New Jersey with its principal place of business at 107 College Road  
6 East, Princeton, NJ 08540.

7           7. Defendant Dr. Reddy's Laboratories, Ltd. is an Indian public limited  
8 liability company organized and existing under the laws of India and having a principal place of  
9 business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 500 034, India.

10 **B. THE ASSERTED PATENTS**

11           8. Amarin Pharmaceuticals Ireland Limited is the owner of the Asserted  
12 Patents.<sup>3</sup>

13           9. Each of the Asserted Patents is entitled "METHODS OF TREATING  
14 HYPERTRIGLYCERIDEMIA."

15           10. The U.S. Applications that ultimately issued as the Asserted Patents are  
16 continuations of U.S. Application No. 12/702,889, filed on February 9, 2010, which ultimately  
17 issued as U.S. Patent No. 8,293,727 ("the '727 Patent").

18           11. The Asserted Patents further claim priority to U.S. Provisional Application  
19 No. 61/151,291, filed on February 10, 2009, and U.S. Provisional Application No. 61/173,755,  
20 filed on April 29, 2009.

21           12. Mehar Manku, Ian Osterloh, Pierre Wicker, Rene Braeckman, and Paresh  
22 Soni are named as inventors of the Asserted Patents.

23  
24  
25 <sup>3</sup> U.S. Patent No. 8,293,728 ("the '728 Patent"), U.S. Patent No. 8,318,715 ("the '715  
26 Patent"), U.S. Patent No. 8,357,677 ("the '677 Patent"), U.S. Patent No. 8,367,652 ("the '652  
27 Patent"), U.S. Patent No. 8,431,560 ("the '560 Patent"), and U.S. Patent No. 8,518,929 ("the  
28 '929 Patent")

1           13. Pursuant to 21 U.S.C. § 355(b)(1), the Asserted Patents are listed in the  
2 Orange Book—published by FDA and formally known as *Approved Drug Products with*  
3 *Therapeutic Equivalence Evaluations*—in connection with New Drug Application (“NDA”) No.  
4 202057.

5           **1. The '728 Patent**

6           14. The PTO issued the '728 Patent on October 23, 2012.

7           15. Amarin Pharmaceuticals Ireland Limited filed U.S. Application No.  
8 13/349,153, which ultimately issued as the '728 Patent, on January 12, 2012.

9           16. U.S. Application No. 13/349,153 is a continuation of U.S. Application No.  
10 12/702,889, filed on February 9, 2010, now the '727 Patent.

11           **2. The '715 Patent**

12           17. The PTO issued the '715 Patent on November 27, 2012.

13           18. The PTO issued a Certificate of Correction to the '715 Patent on August  
14 11, 2015.

15           19. The PTO issued a Certificate of Correction to the '715 Patent on May 21,  
16 2019.

17           20. Amarin Pharmaceuticals Ireland Limited filed U.S. Application No.  
18 13/282,145, which ultimately issued as the '715 Patent, on October 26, 2011.

19           21. U.S. Application No. 13/282,145 is a continuation of U.S. Application No.  
20 12/702,889, filed on February 9, 2010, now the '727 Patent.

21           **3. The '677 Patent**

22           22. The PTO issued the '677 Patent on January 22, 2013.

23           23. Amarin Pharmaceuticals Ireland Limited filed U.S. Application No.  
24 13/608,775, which ultimately issued as the '677 Patent, on September 10, 2012.

25           24. U.S. Application No. 13/608,775 is a continuation of U.S. Application No.  
26 13/349,153, filed on January 12, 2012, now the '728 Patent, which is a continuation of U.S.  
27 Application No. 12/702,889, filed on February 9, 2010, now the '727 Patent.

28

1           **4. The '652 Patent**

2                 25.    The PTO issued the '652 Patent on February 5, 2013.

3                 26.    Amarin Pharmaceuticals Ireland Limited filed U.S. Application No.  
4   13/610,247, which ultimately issued as the '652 Patent, on September 11, 2012.

5                 27.    U.S. Application No. 13/610,247 is a continuation of U.S. Application No.  
6   13/349,153, filed on January 12, 2012, now the '728 Patent, which is a continuation of U.S.  
7   Application No. 12/702,889, filed on February 9, 2010, now the '727 Patent.

8           **5. The '560 Patent**

9                 28.    The PTO issued the '560 Patent on April 30, 2013.

10                29.    Amarin Pharmaceuticals Ireland Limited filed U.S. Application No.  
11   13/711,329, which ultimately issued as the '560 Patent, on December 11, 2012.

12                30.    U.S. Application No. 13/711,329 is a continuation of U.S. Application No.  
13   13/623,450, filed on September 20, 2012, now the '920 Patent, which is a continuation of U.S.  
14   Application No. 13/349,153, filed on January 12, 2012, now the '728 Patent, which is a  
15   continuation of U.S. Application No. 12/702,889, filed on February 9, 2010, now the '727  
16   Patent.

17           **6. The '929 Patent**

18                31.    The PTO issued the '929 Patent on August 27, 2013.

19                32.    Amarin Pharmaceuticals Ireland Limited filed U.S. Application No.  
20   13/776,242, which ultimately issued as the '929 Patent, on February 25, 2013.

21                33.    U.S. Application No. 13/776,242 is a continuation of U.S. Application No.  
22   13/711,329, filed on December 11, 2012, now the '560 Patent, which is a continuation of U.S.  
23   Application No. 13/623,450, filed on September 20, 2012, now the '920 Patent, which is a  
24   continuation of U.S. Application No. 13/349,153, filed on January 12, 2012, now the '728  
25   Patent, which is a continuation of U.S. Application No. 12/702,889, filed on February 9, 2010,  
26   now the '727 Patent.

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