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14 Attorneys for Plaintiffs  
SPECTRUM PHARMACEUTICALS, INC.  
15 AND UNIVERSITY OF STRATHCLYDE

16  
17 **UNITED STATES DISTRICT COURT**  
18 **DISTRICT OF NEVADA**

19 SPECTRUM PHARMACEUTICALS, INC. )  
20 and UNIVERSITY OF STRATHCLYDE, )  
)  
21 Plaintiffs, )  
)  
22 v. )  
)  
23 BEN VENUE LABORATORIES, INC. )  
d/b/a BEDFORD LABORATORIES )  
24 )  
Defendants. )

Case No.: 2:14-cv-00980

**COMPLAINT FOR  
PATENT INFRINGEMENT**

25  
26  
27  
28

1 Plaintiffs Spectrum Pharmaceuticals, Inc. (“Spectrum”) and University of Strathclyde  
2 (“Strathclyde”) (collectively “Plaintiffs”), by their undersigned attorneys, for their Complaint  
3 against Defendant Ben Venue Laboratories, Inc. (“Ben Venue”), allege:

4 **NATURE OF THE ACTION**

5 1. This is an action for patent infringement under the patent laws of the United  
6 States, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(e)(2), and the Declaratory Judgment  
7 Act, 28 U.S.C. §§ 2201 and 2202, arising from Ben Venue’s filing of an Abbreviated New Drug  
8 Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21  
9 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market a  
10 levoleucovorin product, which is a generic form of Spectrum’s pharmaceutical product Fusilev<sup>®</sup>,  
11 prior to the expiration of United States Patent No. 6,500,829 (“the ‘829 patent”), which covers  
12 Fusilev<sup>®</sup>.

13 **THE PARTIES**

14 2. Spectrum is a Delaware corporation having its principal place of business at  
15 11500 South Eastern Avenue, Suite 240, Henderson, Nevada 89052. Spectrum is engaged in the  
16 business of research, development, manufacture, and sale of pharmaceutical products.

17 3. Strathclyde, incorporated by Royal Charter of Queen Elisabeth II, is a charitable  
18 body registered in Scotland with registration number SC015263, having its principal place of  
19 business at 16 Richmond Street, Glasgow G1 1XQ, Scotland, United Kingdom.

20 4. Upon information and belief, Bedford Laboratories (“Bedford”) is an  
21 unincorporated division of Ben Venue Laboratories, Inc., a corporation organized and existing  
22 under the laws of the State of Delaware, both having a place of business at 300 Northfield Road,  
23 Bedford, Ohio 44146.

24 5. Upon information and belief, Ben Venue, directly and/or through Bedford,  
25 markets, manufactures, distributes, and sells generic drugs for use in the State of Nevada and  
26 throughout the United States.

27 **JURISDICTION AND VENUE**

28 6. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C.

1 §§ 1331, 1338(a), 2201 and 2202.

2 7. This Court has personal jurisdiction over Ben Venue. Ben Venue has purposefully  
3 conducted and continues to conduct business in this District, including by having availed itself of  
4 the rights, protections, and benefits of Nevada law, such that it should reasonably anticipate  
5 being haled into court in this District.

6 8. On information and belief, Ben Venue through Bedford applied for, and received  
7 a license from the Nevada Board of Pharmacy to act as a pharmaceutical wholesaler in Nevada.  
8 On information and belief, Ben Venue through Bedford is currently a registered "Wholesaler" of  
9 drug products with the Nevada Board of Pharmacy, and distributes drug products throughout the  
10 State of Nevada. Ben Venue directly and/or through Bedford has systematic and continuous  
11 contacts with the State of Nevada, by including, among other things, selling pharmaceutical  
12 products to residents of Nevada, and to others with the intent that those products are marketed  
13 and distributed in Nevada, and receiving significant revenue for the sale of those products in  
14 Nevada.

15 9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

16 **THE PATENT-IN-SUIT**

17 10. On December 31, 2002, the United States Patent and Trademark Office issued  
18 U.S. Patent No. 6,500,829, entitled "Substantially Pure Diastereoisomers of Tetrahydrofolate  
19 Derivatives." At the time of its issue, the '829 patent was assigned to Strathclyde. Strathclyde  
20 currently holds title to the '829 patent. Strathclyde has exclusively licensed the '829 patent to  
21 Spectrum. A copy of the '829 patent is attached hereto as Exhibit A.

22 11. The claims of the '829 patent are valid and enforceable.

23 **FUSILEV<sup>®</sup>**

24 12. Spectrum holds New Drug Application No. 20-140 (initially approved on March  
25 7, 2008) ("the Fusilev<sup>®</sup> NDA") approving Spectrum to market a levoleucovorin product as a  
26 lyophilized powder in a 50 mg dosage strength, which is marketed by Spectrum under the trade  
27 name Fusilev<sup>®</sup>.

28 13. On November 7, 2011, the FDA granted Fusilev<sup>®</sup> seven years of orphan-drug

1 exclusive approval pursuant to Section 527 of the Federal Food, Drug, and Cosmetic Act (21  
2 U.S.C. § 360cc) for use in combination chemotherapy with 5-fluorouracil in the palliative  
3 treatment of advanced metastatic adenocarcinoma of the colon and rectum.

4 14. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '829 patent  
5 is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence  
6 Evaluations" ("the Orange Book") with respect to Fusilev<sup>®</sup>.

7 **BEN VENUE'S ANDA**

8 15. On information and belief, Ben Venue submitted an Abbreviated New Drug  
9 Application, ANDA No. 206263, to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval  
10 to market levoleucovorin calcium for injection, 50 mg/vial ("Ben Venue's ANDA"). The  
11 levoleucovorin vial described in Ben Venue's ANDA are herein referred to as "Ben Venue's  
12 Product."

13 16. On information and belief, Ben Venue's ANDA refers to and relies upon the  
14 Fusilev<sup>®</sup> NDA and/or the Fusilev<sup>®</sup> sNDA and contains data that, according to Ben Venue,  
15 demonstrates the bioequivalence of Ben Venue's Product and Fusilev<sup>®</sup>.

16 17. By filing Ben Venue's ANDA, Ben Venue has necessarily represented to the  
17 FDA that Ben Venue's Product has the same active ingredient as Fusilev<sup>®</sup>, has the same route of  
18 administration, dosage form, and strength as Fusilev<sup>®</sup>, is bioequivalent to Fusilev<sup>®</sup>, and has the  
19 same or substantially the same proposed labeling as Fusilev<sup>®</sup>.

20 18. Spectrum received a letter from Ben Venue on or around June 11, 2014 ("Ben  
21 Venue's Notification"), stating that Ben Venue had included a certification in Ben Venue's  
22 ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '829 patent is invalid,  
23 unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Ben  
24 Venue's Product.

25 19. This action is being brought within forty-five days from the date that Spectrum  
26 received Ben Venue's Notification.

27 **COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,500,829**

28 20. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-19

1 of this Complaint.

2 21. The '829 patent contains claims directed to, for example (claim 1), "A  
3 pharmaceutical composition for therapeutic use which consists essentially of a therapeutically  
4 effective amount sufficient for the treatment of human beings for methotrexate rescue or folate  
5 deficiency, of a pharmaceutically acceptable compound which is a (6S) diastereoisomer selected  
6 from the group consisting of (6S) leucovorin (5-formyl-(6S)-tetrahydrofolic acid) and  
7 pharmaceutically acceptable salts and esters of (6S) leucovorin; wherein the compound consists  
8 of a mixture of (6S) and (6R) diastereoisomers and consists of at least 92% by weight of the (6S)  
9 diastereoisomer, the balance of said compound consisting of the (6R) diastereoisomer; in  
10 combination with a pharmaceutically acceptable carrier."

11 22. Ben Venue infringes claims 1 and 2 of the '829 patent, and does not deny such  
12 infringement in Ben Venue's Notification.

13 23. Ben Venue has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A)  
14 by submitting Ben Venue's ANDA, by which Ben Venue seeks approval from the FDA to  
15 engage in the commercial manufacture, use, offer to sell, sale, or importation of Ben Venue's  
16 Product prior to the expiration of the '829 patent.

17 24. Ben Venue's commercial manufacture, use, offer to sell, or sale of Ben Venue's  
18 Product within the United States, or importation of Ben Venue's Product into the United States,  
19 during the term of the '829 patent would further infringe one or more claims of the '829 patent  
20 under 35 U.S.C. §§ 271(a), (b), and/or (c).

21 25. Ben Venue's filing of Ben Venue's ANDA and its intention to engage in the  
22 commercial manufacture, use, offer to sell, sale, or importation of Ben Venue's Product upon  
23 receiving FDA approval creates an actual case or controversy with respect to infringement of the  
24 '829 patent.

25 26. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an  
26 order of this Court that the effective date of any approval relating to Ben Venue's ANDA shall  
27 not be earlier than March 7, 2022, the current expiration date of the '829 patent, or any later  
28 expiration date to which Plaintiffs become entitled.



1 their reasonable attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285 and 271(e)(4);

2 I. Reasonable filing fees, costs and expenses incurred by Plaintiffs in this action;  
3 and

4 J. Such further and other relief as this Court deems just and proper.  
5

6 Dated: this 18th day of June, 2014.

7 Respectfully submitted,

8 LEWIS ROCA ROTHGERBER LLP  
9

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