Michael J. McCue (Nevada Bar #6055)
Jonathan W. Fountain (Nevada Bar #10351)
LEWIS AND ROCA LLP
3993 Howard Hughes Parkway, Suite 600
Las Vegas, NV 89169-5996
(702) 949-8200 (phone)
(702) 949-8398 (facsimile)
mmccue@lrlaw.com
jfountain@lrlaw.com

Mark H. Izraelewicz (*pro hac vice* application to be filed)
Kevin M. Flowers (*pro hac vice* application to be filed)
Cullen N. Pendleton (*pro hac vice* application to be filed)
Amanda Antons (*pro hac vice* application to be filed)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive, 6300 Willis Tower
Chicago, IL 60606-6357
(312) 474-6300 (phone)
(312) 474-0448 (facsimile)
mizraelewicz@marshallip.com
kflowers@marshallip.com
cpendleton@marshallip.com
aantons@marshallip.com

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

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

SPECTRUM PHARMACEUTICALS, INC. and UNIVERSITY OF STRATHCLYDE, Plaintiffs, v. SANDOZ INC., Defendant.	**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Spectrum Pharmaceuticals, Inc. ("Spectrum") and University of Strathclyde ("Strathclyde") (collectively "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Sandoz Inc. ("Sandoz"), herein allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, arising from Sandoz's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market levoleucovorin products, which are generic forms of Spectrum's pharmaceutical product Fusilev®, prior to the expiration of United States Patent No. 6,500,829 ("the '829 patent"), which covers Fusilev®.

THE PARTIES

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

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

4. On information and belief, Sandoz is a corporation organized under the laws of Colorado.

5. On information and belief, Sandoz is in the business of making and selling generic pharmaceutical products, which it markets and sells in this District and throughout the United States.

JURISDICTION AND VENUE

6. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

7. This Court has personal jurisdiction over Sandoz. Sandoz has purposefully

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Suite 600
Las Vegas, Nevada 89169

conducted and continues to conduct business in this District, including by having availed itself of the rights, protections, and benefits of Nevada law, such that it should reasonably anticipate being haled into court in this District. Sandoz has systematic and continuous contacts with the State of Nevada, by including, among other things, selling pharmaceutical products to residents of Nevada, and to others with the intent that those products are marketed and distributed in Nevada, and receiving significant revenue for the sale of those products in Nevada.

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

THE PATENT-IN-SUIT

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

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

FUSILEV®

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

12. On April 20, 2011, the FDA granted Spectrum's supplemental New Drug Application (submitted on December 22, 2010) approving Spectrum to market Fusilev® in 175 mg and 250 mg dosage strengths as solutions for intravenous infusion ("the Fusilev® sNDA").

13. The FDA approved the 175 mg and 250 mg dosage strengths to treat patients diagnosed with advanced metastatic colorectal cancer.

14. On November 7, 2011, the FDA granted Fusilev® seven years of orphan-drug exclusive approval pursuant to Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360cc) for use in combination chemotherapy with 5-fluorouracil in the palliative treatment of advanced metastatic adenocarcinoma of the colon and rectum.

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

SANDOZ'S ANDA

16. On information and belief, Sandoz submitted an Abbreviated New Drug Application, ANDA No. 203563, to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market "ready to use" vials of levoleucovorin with 175 mg and 250 mg dosage strengths ("Sandoz's ANDA"). The levoleucovorin vials described in Sandoz's ANDA are herein referred to as "Sandoz's Products."

17. On information and belief, Sandoz's ANDA refers to and relies upon the Fusilev® NDA and/or the Fusilev® sNDA and contains data that, according to Sandoz, demonstrates the bioequivalence of Sandoz's Products and Fusilev®.

18. By filing Sandoz's ANDA, Sandoz has necessarily represented to the FDA that Sandoz's Products have the same active ingredient as Fusilev®, have the same routes of administration, dosage forms, and strengths as Fusilev®, are bioequivalent to Fusilev®, and have the same or substantially the same proposed labeling as Fusilev®.

19. Spectrum received a letter from Sandoz on or around December 13, 2011, and an attached memorandum (collectively, "Sandoz's Notification"), stating that Sandoz had included a certification in Sandoz's ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '829 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Sandoz's Products.

20. This action is being brought within forty-five days from the date that Spectrum received Sandoz's Notification.

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

21. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-20 of this Complaint.

22. The '829 patent contains claims directed to, for example (claim 1), "A pharmaceutical composition for therapeutic use which consists essentially of a therapeutically

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effective amount sufficient for the treatment of human beings for methotrexate rescue or folate deficiency, of a pharmaceutically acceptable compound which is a (6S) diastereoisomer selected from the group consisting of (6S) leucovorin (5-formyl-(6S)-tetrahydrofolic acid) and pharmaceutically acceptable salts and esters of (6S) leucovorin; wherein the compound consists of a mixture of (6S) and (6R) diastereoisomers and consists of at least 92% by weight of the (6S) diastereoisomer, the balance of said compound consisting of the (6R) diastereoisomer; in combination with a pharmaceutically acceptable carrier."

23. In Sandoz's Notification, Sandoz did not allege that Sandoz's Products do not infringe claims 1 and 2 of the '829 patent.

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

25. Sandoz's commercial manufacture, use, offer to sell, or sale of Sandoz's Products within the United States, or importation of Sandoz's Products into the United States, during the term of the '829 patent would further infringe one or more claims of the '829 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

26. Sandoz's filing of Sandoz's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '829 patent.

27. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Sandoz's ANDA shall not be earlier than December 31, 2019, the current expiration date of the '829 patent, or any later expiration date to which Plaintiffs become entitled.

28. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees, under 35 U.S.C. § 285.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

A. A declaration that the '829 patent is valid and enforceable;

B. A declaration that by filing Sandoz's ANDA, Sandoz has infringed one or more claims of the '829 patent under 35 U.S.C. § 271(e)(2)(A);

C. A declaration that one or more claims of the '829 patent would be infringed by the manufacture, use, offer for sale, or sale of Sandoz's Products within the United States, or by importation of Sandoz's Products into the United States;

D. An Order preliminarily and permanently enjoining Sandoz, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Sandoz's Products within the United States, or importing Sandoz's Products into the United States, prior to the expiration of the '829 patent (including any extensions thereof);

E. An Order prohibiting Sandoz, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from seeking, obtaining, or maintaining approval of Sandoz's ANDA, prior to the expiration of the '829 patent (including any extensions thereof);

F. A declaration that the effective date of any approval of Sandoz's ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '829 patent (including any extensions thereof);

G. A judgment awarding Plaintiffs damages or other monetary relief if Sandoz commercially manufactures, uses, offers to sell, or sells Sandoz's Products within the United States, or imports Sandoz's Products into the United States, prior to the expiration of the '829 patent (including any extensions thereof), and that any such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment interest;

H. A declaration that this is an exceptional case and a judgment awarding Plaintiffs their reasonable attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285 and 271(e)(4);

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

Lewis and Roca LLP
3993 Howard Hughes Parkway
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Las Vegas, Nevada 89169

and

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

Dated: this 20th day of January, 2012.

Respectfully submitted,

LEWIS AND ROCA LLP

By: /s/ Michael J. McCue

Michael J. McCue (Nevada Bar #6055)
Jonathan W. Fountain (Nevada Bar #10351)
3993 Howard Hughes Parkway, Suite 600
Las Vegas, NV 89169-5996
(702) 949-8200 (phone)
(702) 949-8398 (facsimile)
mmccue@lrlaw.com
jfountain@lrlaw.com

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233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357
(312) 474-6300 (phone)
(312) 474-0448 (facsimile)
mizraelewicz@marshallip.com
kflowers@marshallip.com
cpendleton@marshallip.com
aantons@marshallip.com

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