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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

ASCIO PHARMACEUTICALS, INC.)
)
Plaintiff,)
)
v.)
)
THREE RIVERS)
PHARMACEUTICALS, LLC)
)
Defendant.)

TCB

Civil Action File No.: 10-CV-1583

**ASCIO PHARMACEUTICALS' COMPLAINT
FOR DECLARATORY JUDGMENT**

Plaintiff Ascio Pharmaceuticals, Inc. ("Ascio") for its Complaint against
Three Rivers Pharmaceuticals, LLC ("Three Rivers") alleges as follows:

PARTIES

1.

Plaintiff Ascio is a corporation organized under the laws of the State of Delaware with its principal place of business at 2475 Northwinds Pkwy, Suite 200, Alpharetta, GA 30004.

2.

Upon information and belief, Defendant Three Rivers is a corporation organized

under the laws of the State of Pennsylvania having its principal place of business at 119 Commonwealth Drive, Warrendale, PA 15086. Three Rivers is engaged in the business of the sale of pharmaceutical products throughout the U.S.

BACKGROUND

3.

Three Rivers is a generic drug company that manufactures and sells, among other things, several forms of the drug ribavirin, which Three Rivers primarily markets for the treatment of hepatitis C. Three Rivers markets 400 mg and 600 mg ribavirin tablets under the names Ribapak[®] and Ribasphere[®].

4.

Upon information and belief, Three Rivers is the holder of approved Abbreviated New Drug Application (“ANDA”) No. 77-456 for 200 mg, 400 mg, and 600 mg ribavirin tablets.

5.

Three Rivers is also the assignee of U.S. Patent No. 7,723,310 (“the ‘310 Patent”) titled “Large Dose Ribavirin Formulations,” which includes claims directed to methods of treating a hepatitis C virus infection with large dosage forms of ribavirin, including 400 mg and 600 mg dosage forms, and interferon alfa-2a or alfa-2b.

6.

Ascio is also a generic drug manufacturer.

7.

Ascio filed an ANDA to sell a generic version of Three Rivers' 600 mg ribavirin tablets as well as 500 mg ribavirin tablets. The ANDA number is 90-989, and it is currently pending at the U.S. Food & Drug Administration.

8.

Prompted by Ascio's ANDA filing, Three Rivers contacted Ascio, asserting that Ascio's intended sale of large dosage forms of ribavirin would infringe the '310 Patent and threatening to sue Ascio if it sells 400 mg or 600 mg dosage forms of ribavirin.

9.

Ascio brings, and is entitled by statute to maintain, this action for declaratory judgment of non-infringement, invalidity, and unenforceability of the '310 Patent under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

10.

Ascio is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Ascio's proposed 500 mg and 600 mg ribavirin tablets do not and will not infringe any valid and enforceable claim of the '310 Patent.

JURISDICTION AND VENUE

11.

Ascio realleges and incorporates by reference each of the allegations of paragraphs 1-10.

12.

A substantial, present, genuine, and justiciable controversy exists between Ascio and Three Rivers with respect to the '310 Patent.

13.

On November 2, 2009, Three Rivers' counsel, Janine Carlan, sent Ascio's President and Chief Executive Officer, Keith Watts, a letter advising and putting Ascio "on notice" of Three Rivers' U.S. Patent Nos. 6,720,000 ("the '000 Patent") and 7,538,094 ("the '094 Patent") and U.S. Application Publication Nos. 2006/0083785 ("the '785 Application") and 2007/0161583 ("the '583 Application"). The '785 Application matured into the '310 Patent. A copy of the letter is attached as Exhibit A.

14.

According to the letter, it had recently come to Three Rivers' attention that Ascio intended to market and sell ribavirin products. Exhibit A, p. 1.

15.

In the letter, Three Rivers stated that:

[T]he '785 and '583 patent applications, when issued will cover single dosage forms of ribavirin comprising 400 mg and 600 mg of ribavirin. Pursuant to 35 U.S.C. § 154(d), Three Rivers may have provisional patent rights including the right to recover reasonable royalties for the sale of 400 mg and 600 mg ribavirin tablets occurring *prior* to the issuance of the '785 and '583 applications as a patent.

Exhibit A, p. 1 (emphasis in original).

16.

Three Rivers' counsel further informed Ascio that Three Rivers would avail itself of all available remedies to enforce its intellectual property:

Finally, be assured that Three Rivers takes this matter very seriously, and it will, if necessary, avail itself of all available remedies to enforce its intellectual property. Your cooperation in this matter is appreciated.

Exhibit A, p. 2.

17.

This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

18.

This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because this action involves substantial claims arising

under the United States Patent Act, 35 U.S.C. § 1 *et seq.*, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because it is an actual controversy concerning the '310 Patent.

19.

This Court has personal jurisdiction over Three Rivers, *inter alia*, because of Three Rivers' continuous and systematic contacts with the State of Georgia, including its conducting of substantial and regular business therein through the marketing and sales of its pharmaceutical products throughout the state and in this District.

20.

Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) and/or 1400(b).

THREE RIVERS' PROSECUTION OF THE PATENT IN SUIT

21.

The '310 Patent relates generally to an alleged improvement in the treatment of hepatitis C.

22.

One standard treatment regimen for hepatitis C involves administering an anti-viral drug, ribavirin, in conjunction with another medication, interferon, where the patient takes three 200 mg ribavirin pills two times a day.

23.

Three Rivers' improvement on this regimen is providing the patient with a single 600 mg pill in place of the three 200 mg pills.

24.

More specifically, the '310 Patent is directed toward large dosage forms of ribavirin for use in treating hepatitis C. By way of example, the two independent claims (claims 1 and 9) of the '310 Patent read as follows:

1. A method of treating a hepatitis-C virus infection with ribavirin administered in combination with interferon alfa-2a or alfa-2b in a patient in need thereof, the ribavirin administration consisting of administering to the patient exactly one dosage form comprising 400 mg to 600 mg of ribavirin twice daily.

9. In a method of treating a hepatitis-C virus infection in a patient in need thereof comprising administering to the patient interferon alfa-2a or alfa-2b and a daily divided dose of 4 to 6 dosage forms each containing 200 mg ribavirin, the improvement consisting of administering to the patient exactly one dosage form comprising 400 mg to 600 mg of ribavirin twice daily instead of the daily divided dose of 4 to 6 dosage forms each containing 200 mg ribavirin.

25.

The dependent claims in the '310 Patent recite properties (such as hardness) and components of the dosage form (claims 2-5), dispensing the dosage forms in a bottle, unit dose package, or blister pack (claims 6-8, 13, and 14), and dosage form (a tablet) and strength (claims 10-12 and 15-17).

**THREE RIVERS' INEQUITABLE CONDUCT
DURING THE PROSECUTION OF THE PATENT IN SUIT**

26.

The application that matured into the '310 Patent was filed on August 11, 2005 by Three Rivers' patent prosecution attorney, Richard Berman of Arent Fox PLLC.

27.

Less than two years later, and while he was still prosecuting the '310 Patent, on March 30, 2007, the same attorney filed a co-pending patent application, U.S. Serial No. 11/693,993 ("the '993 Application") that is related to the '310 Patent.

28.

Many of the claims in the '993 Application are substantially similar in all material respects to the claims of the '310 Patent.

29.

For example, claim 1 of the '310 Patent and claim 23 of the '993 Application, shown below, include all of the same material limitations:

U.S. Patent No. 7,723,310

Claim 1. A method of treating a hepatitis-C virus infection with ribavirin administered in combination with interferon alfa-2a or alfa-2b in a patient in need thereof, the ribavirin administration consisting of **administering** to the patient **exactly one dosage form comprising 400 mg to 600 mg of ribavirin twice daily.**

U.S. Application No. 11/693,993

Claim 23. A daily dosage regimen of ribavirin combination treatment with an interferon for hepatitis-C virus (HCV) therapy, comprising **administering twice a day** to a patient in need thereof **exactly one dosage form comprising 400 mg or 600 mg of ribavirin,** wherein the 400 mg dosage form is bioequivalent to two 200 mg immediate release dosage forms and the 600 mg dosage form is bioequivalent to three 200 mg immediate release dosage forms.

30.

Claim 1 of the '310 Patent and claim 23 of the '993 Application are patentably indistinct.

31.

The '310 Patent and the '993 Application were assigned to different examiners at the USPTO.

32.

Notwithstanding the different examiners, the claims in both the '310 Patent and the '993 Application were rejected as unpatentable under 35 U.S.C. § 103 due to obviousness in view of Leibowitz, U.S. Patent No. 6,337,090.

33.

In the '310 Patent, the rejection was included in an October 30, 2009 Non-Final Rejection.

34.

In the '993 Application, the rejection was included in both a July 25, 2007 Non-Final Rejection and a September 20, 2007 Final Rejection.

35.

In both cases, in response to these rejections, Three Rivers submitted evidence of the alleged commercial success of its Ribapak[®] products as a secondary consideration of non-obviousness intended to overcome the obviousness rejections.

36.

The Examiner of the '310 Patent accepted the evidence of alleged commercial success and issued a Notice of Allowance on March 23, 2010.

37.

To the contrary, the Examiner of the '993 Application did not find the evidence of commercial success sufficient to overcome the obviousness rejection, and maintained the rejection.

38.

In the '993 Application, the Examiner's rejection of the evidence of secondary

considerations of non-obviousness was embodied in both the September 20, 2007 Final Rejection and the May 15, 2008 Examiner's Answer to Appeal Brief filed by the Examiner in Three River's appeal of the Final Rejection.

39.

Despite the fact that another Examiner had filed two documents analyzing the exact same evidence as it relates to materially identical claims, Three Rivers and its prosecuting attorney never disclosed either the Final Rejection or the Examiner's Answer from the '993 Application to the Examiner of the '310 Patent.

40.

Ascio's counsel wrote to Three Rivers' prosecuting attorney on March 26, 2010 noting this lack of disclosure and informing Three Rivers and its prosecuting attorney of their obligation to disclose the adverse decisions in the '993 Application to the Examiner of the '310 Patent. A copy of Ascio's March 26, 2010 letter is attached as Exhibit B.

41.

Three Rivers and its prosecuting attorney never disclosed the adverse decisions or the March 26, 2010 letter to the Patent Office.

42.

Three Rivers and its prosecuting attorney were required to disclose the adverse

decisions and the March 26, 2010 letter to the Patent Office in connection with the '310 Patent.

43.

Three Rivers had disclosed to the Patent Office other information brought to its attention by Ascio in an earlier letter in a February 17, 2010 Information Disclosure Statement.

44.

Two days after receiving the Notice of Allowance for the '310 Patent, Three Rivers expressly abandoned the '993 Application.

COUNT 1
UNENFORCEABILITY OF THE '310 PATENT
DUE TO INEQUITABLE CONDUCT

45.

Ascio realleges and incorporates by reference each of the allegations of paragraphs 1-44.

46.

The '310 Patent is unenforceable due to Three Rivers' inequitable conduct during the prosecution of the '310 Patent.

47.

On information and belief, Three Rivers and its prosecuting attorney failed to

disclose material information to the Patent Office during the prosecution of the '310 Patent with the intent to deceive the Patent Office.

48.

Specifically, during the prosecution of the '310 Patent, Three Rivers and its prosecuting attorney failed to disclose to the Examiner of the '310 Patent the July 25, 2007 Non-Final Rejection, the September 20, 2007 Final Rejection, and the May 15, 2008 Examiner's Answer to Appeal Brief filed by the Examiner of the '993 Application.

49.

The July 25, 2007 Non-Final Rejection was material to the prosecution of the '310 Patent.

50.

The July 25, 2007 Non-Final Rejection was material to the prosecution of the '310 Patent because it related to the rejection of claims that were patentably indistinct from the claims of the '310 Patent.

51.

The September 20, 2007 Final Rejection was material to the prosecution of the '310 Patent.

52.

The September 20, 2007 Final Rejection was material to the prosecution of the '310 Patent because it related to the rejection of claims that were patentably indistinct from the claims of the '310 Patent.

53.

The May 15, 2008 Examiner's Answer to Appeal Brief was material to the prosecution of the '310 Patent.

54.

The May 15, 2008 Examiner's Answer to Appeal Brief was material to the prosecution of the '310 Patent because it related to the rejection of claims that were patentably indistinct from the claims of the '310 Patent.

55.

Three Rivers and its prosecuting attorney failed to disclose the March 26, 2010 letter from Ascio's counsel regarding Three Rivers' disclosure obligations to the Examiner of the '310 Patent.

56.

The March 26, 2010 letter was material to the prosecution of the '310 Patent.

57.

Pursuant to the Manual of Patent Examining Procedure ("MPEP") § 2001.04,

Three Rivers' obligation to disclose material information continued even after the March 23, 2010 Notice of Allowance.

58.

On information and belief, the same attorney for Three Rivers was at all times responsible for the prosecution of both the '310 Patent and the '993 Application.

59.

On information and belief, despite disclosing Ascio's counsel's February 1, 2010 letter to the Patent Office, and despite being aware of their continuing obligation to make such disclosures, Three Rivers and its prosecuting attorney did not disclose the March 26, 2010 letter because they intended to deceive the Patent Office

60.

On information and belief, Three Rivers withheld material information because the disclosure of the information might have prevented the '310 Patent from issuing.

61.

Three Rivers expressly abandoned the '993 Application two days after the Notice of Allowance of the '310 Patent.

62.

On information and belief, Three Rivers abandoned the '993 Application because

Three Rivers' intention was to pursue two separate applications in the hopes that at least one would issue.

63.

On information and belief, Three Rivers' failure to disclose the July 25, 2007 Non-Final Rejection, the September 20, 2007 Final Rejection, the May 15, 2008 Examiner's Answer, and the March 26, 2010 letter were all done with intent to deceive the Patent Office.

64.

Three Rivers' intentional failure to disclose material information to the Patent Office during the prosecution of the '310 Patent renders the '310 Patent unenforceable.

65.

By reason of the foregoing, Ascio is entitled to an entry of judgment pursuant to 28 U.S.C. §§ 2201 and 2202 declaring the '310 Patent unenforceable.

COUNT 2
INVALIDITY OF THE '310 PATENT

66.

Ascio realleges and incorporates by reference each of the allegations of paragraphs 1-65.

67.

All of the claims of the '310 Patent are invalid for failure to meet one or more of the conditions of patentability of inventions set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

68.

By reason of the foregoing, Ascio is entitled to an entry of judgment pursuant to 28 U.S.C. §§ 2201 and 2202 declaring the '310 Patent invalid.

COUNT 3
NON-INFRINGEMENT OF THE '310 PATENT

69.

Ascio realleges and incorporates by reference each of the allegations of paragraphs 1-68.

70.

Ascio has not infringed and is not infringing any valid or enforceable claim of the '310 Patent.

71.

By reason of the foregoing, Ascio is entitled to an entry of judgment pursuant to 28 U.S.C. §§ 2201 and 2202 declaring the '310 Patent not infringed.

PRAYER FOR RELIEF

WHEREFORE, Ascio respectfully requests the Court enter judgment and Order in its favor and against Three Rivers to include:

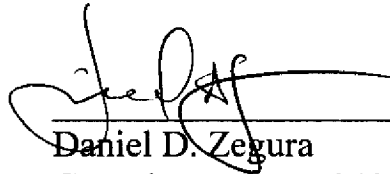
a. A declaration that Ascio's manufacture, use, offer for sale, sale or importation of the 500 and 600 mg ribavirin tablets covered by ANDA No. 90-989 will not infringe any claim of U.S. Patent No. 7,723,310.

b. A declaration that all of the claims of U.S. Patent No. 7,723,310 are invalid.

c. A declaration that U.S. Patent No. 7,723,310 cannot be enforced against Ascio.

d. An award of attorneys' fees, costs, expenses and such other and further relief as the Court may deem just and proper.

This 25th day of May, 2010.



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