71 F.Supp.3d 458
United States District Court,
D. Delaware.

Pfizer Inc., Pharmacia & Upjohn Company, Pharmacia & Upjohn Company LLC, Sugen, Inc., C.P., Pharmaceuticals International C.V., Pfizer Pharmaceuticals LLC, and PF Prism C.V., Plaintiffs,
v.
Mylan Pharmaceuticals Inc., Defendant.

C.A.No. 10–528–GMS
|
Signed October 22, 2014

Synopsis

Background: Patentees brought action against competitor, alleging infringement of patents related to cancer treatment drugs that operated by blocking angiogenesis. Following bench trial, parties moved and cross-moved for judgment on partial findings with respect to issue of validity.

Holdings: The District Court, Gregory M. Sleet, J., held that:

[1] asserted claims were not obvious based on prior patent application disclosing approximately 1,200 drug combinations;

[2] potential "lead compounds" proposed by competitor would not have been selected by one skilled in art;

[3] even if competitor had identified appropriate "lead compound," it failed to establish that modifications to yield claimed compound were obvious; and

[4] even if competitor had established prima facie case of obviousness, secondary considerations weighed against finding of obviousness.

Patentees' motion granted.

Attorneys and Law Firms

***462** Jack B. Blumenfeld, Maryellen Noreika, Morris, Nichols, Arsht & Tunnell, Wilmington, DE, Stanley E. Fisher, Pro Hac Vice, Thomas H.L. Selby, Pro Hac Vice, for Plaintiffs.

Joshua A. Mack, Pro Hac Vice, Katherine Hasper, Pro Hac Vice, Katherine Van Gunst, Pro Hac Vice, Kirin K. Gill, Pro Hac Vice, Robert A. Delafield, II, Pro Hac Vice, Tung–On Kong, Pro Hac Vice, for Defendant.

MEMORANDUM

Gregory M. Sleet, UNITED STATES DISTRICT JUDGE

I. INTRODUCTION

In this patent infringement action, plaintiffs Pfizer Inc., Pharmacia & Upjohn Company, Pharmacia & Upjohn Company LLC, Sugen, Inc., C.P. Pharmaceuticals International C.V., Pfizer Pharmaceuticals LLC, and PF Prism C.V. (collectively, "Pfizer") allege that pharmaceutical products proposed by defendant Mylan Pharmaceuticals Inc. ("Mylan") infringe the asserted claims of the patents-in-suit. (D.I.1.) The court held a four-day bench trial in this matter on November 26 through November 29, 2012. (D.I.148–151.) Presently before the court are the parties' post-trial proposed findings of fact and conclusions of law concerning the validity of the patents-in-suit, specifically whether the asserted claims are invalid as obvious under 35 U.S.C. § 103. (D.I.152, 153.)

Pursuant to Federal Rule of Civil Procedure 52(a), and after having considered the entire record in this case and the applicable law, the court concludes that: (1) all asserted claims of the patents-in-suit are not invalid due to obviousness; and (2) Pfizer's Rule 52(c) motion is granted, and Mylan's Rule 52(c) motion is denied. These findings of fact and conclusions of law are set forth in further detail below.

II. FINDINGS OF FACT [1]

A. The Parties

1. Plaintiff Pfizer Inc. is a corporation organized and existing under the ***463** laws of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

2. Plaintiff Pharmacia & Upjohn Company was a Delaware corporation that was converted into a Delaware limited liability company and changed its name to Pharmacia & Upjohn Company LLC on August 14, 2004. Pharmacia & Upjohn Company LLC has offices located at 7000 Portage Road, Kalamazoo, Michigan 49001.

3. Plaintiff Sugen, Inc. ("Sugen") is a corporation organized under the laws of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

4. Plaintiff C.P. Pharmaceuticals International C.V. ("CPPI CV") is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and registered at the trade register held by the Chamber of Commerce in Rotterdam, under number 24280998. CPPI CV is a wholly owned subsidiary of Pfizer Inc. and has a place of business at 235 East 42nd Street, New York, New York 10017.

5. Plaintiff PF PRISM C.V. ("PF PRISM CV") is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, and registered at the trade register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456.

6. Plaintiff Pfizer Pharmaceuticals LLC is a limited liability company organized under the laws of Delaware and has a place of business at Km 1.9, Road 689, Vega Baja, Puerto Rico 00693. Pfizer Pharmaceuticals LLC is a wholly-owned subsidiary of PF PRISM CV.

7. The plaintiffs will collectively be referred to as "Pfizer."

8. Defendant Mylan Pharmaceuticals Inc. ("Mylan") is a corporation organized and existing under the laws of West Virginia, and has a place of business located at 781 Chestnut Ridge Road, Morgantown, WV 26505.

9. The court has subject matter jurisdiction, as well as personal jurisdiction over all parties.

B. Background

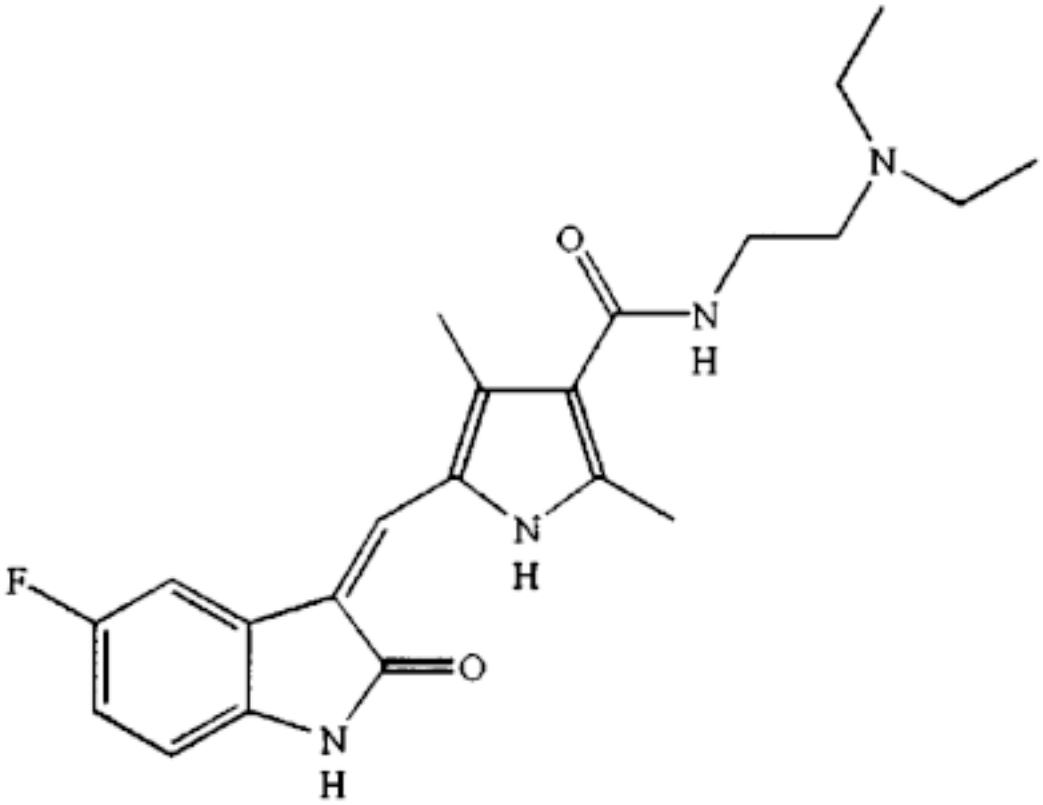
1. The idea of treating cancer by blocking angiogenesis, *i.e.,* the formation of blood vessels, was first suggested in 1971. The concept, however, was still unproven in October 2000, and the FDA had not approved any drug for this purpose.

2. Of the many possible approaches to reduce angiogenesis, one branch of Sugen's research focused on using small molecules to inhibit receptor tyrosine kinases ("RTKs") on the cell surface. Various RTKs bind to external growth factors that promote angiogenesis and tumor growth, such as VEGF (vascular endothelial growth factor), PDGF (platelet ***464** derived growth factor), and FGF (fibroblast growth factor).

3. Sugen's first compound to reach clinical studies was SU5416. It was the first small molecule shown to be effective in treating tumors by inhibiting angiogenesis. SU5416 was not orally bioavailable, meaning it could not be administered to a patient orally, and patients required frequent injections. SU5416 went all the way through FDA Phase III clinical trial but was never approved for market.

4. Sugen synthesized SU11248—what came to known as sunitinib—as part of a research project aimed at attacking tumors directly, rather than through angiogenesis inhibition.

5. Sunitinib has the following chemical structure:



C. The Patents–in–Suit

1. U.S. Patent Number 6,573,293 ("the #293 patent")—"Pyrrole Substituted 2–Indolinone Protein Kinase Inhibitors"—issued on June 3, 2003, to Sugen and Pharmacia & Upjohn Company, as assignees. Sugen is the current owner of the #293 patent.

2. U.S. Application Number 09/783,264 ("the #264 application"), which issued as the #293 patent, was filed on February 15, 2001 with the United States Patent and Trademark Office ("the PTO").

3. The expiration date of the #293 patent is February 15, 2021.

4. The #293 patent lists ten inventors on its face: Peng Cho Tang, Todd A. Miller, Xiaoyuan Li, Li Sun, Chung Chen Wei, Shahrzad Shirazian, Congxin Liang, Tomas Vojkovsky, Asaad S. Nematalla, and Michael Hawley.

5. The #293 patent claims priority back to provisional applications filed on February 15, 2000, July 6, 2000, and October 27, 2000, as Provisional Application Numbers 60/182,710, 60/216,422, and 60/243,532, respectively.

6. Pfizer is asserting infringement of claims 5 and 21 of the #293 patent against Mylan. For purposes of this action, the priority date for asserted claims 5 and 21 is October 27, 2000.

7. U.S. Patent Number 7,125,905 ("the #905 patent")—"Pyrrole Substituted 2–Indolinone Protein Kinase Inhibitors"—issued on October 24, 2006. ***465** Sugen is the current owner of the #905 patent.

8. U.S. Application Number 11/028,477 ("the #477 application"), which issued as the #905 patent, was filed on January 4, 2005 with the PTO. The #477 application is a continuation of Application Number 10/412,690, filed with the PTO on April 14, 2003, now abandoned, which is a division of the #264 application.

9. The expiration date of the #905 patent is February 15, 2021.

10. The #905 patent lists ten inventors on its face: Peng Cho Tang, Todd A. Miller, Xiaoyuan Li, Li Sun, Chung Chen Wei, Shahrzad Shirazian, Congxin Liang, Tomas Vojkovsky, Asaad S. Nematalla, and Michael Hawley.

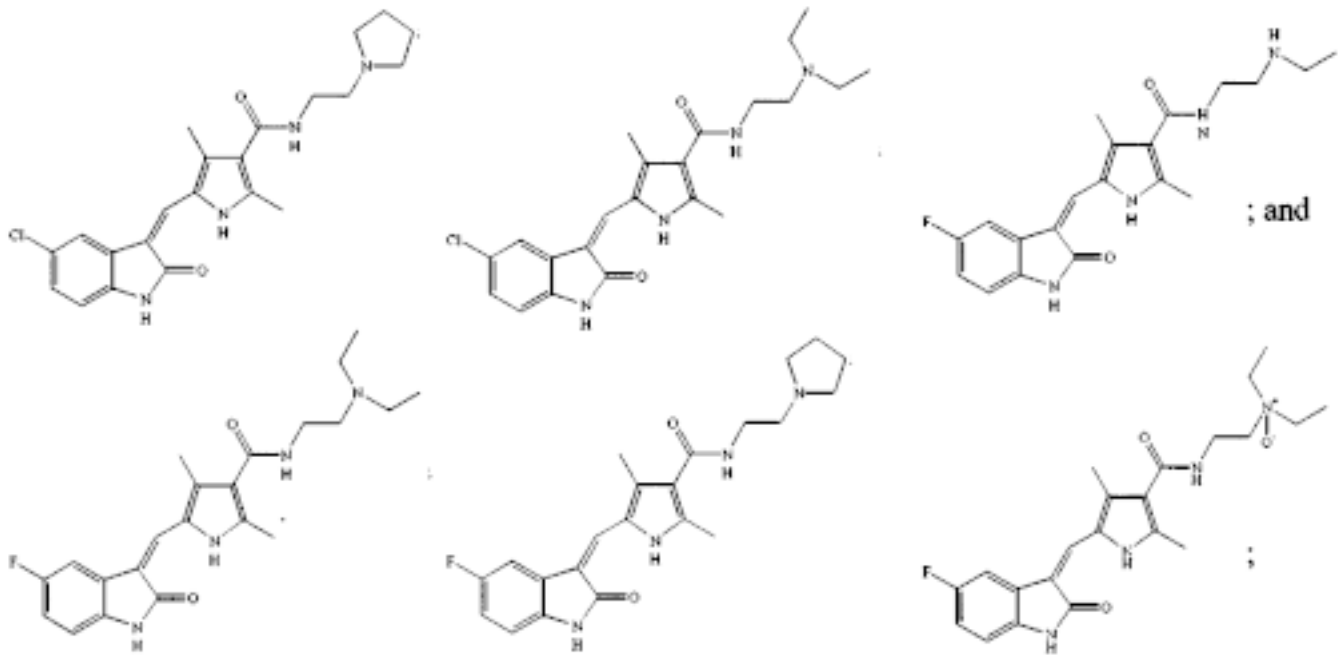
11. The #905 patent also claims priority back to provisional applications filed on February 15, 2000, July 6, 2000, and October 27, 2000, as Provisional Application Numbers 60/182,710, 60/216,422, and 60/243,532, respectively.

12. Pfizer is asserting infringement of claims 1 and 2 of the #905 patent against Mylan. For purposes of this action, the priority date for asserted claims 1 and 2 is October 27, 2000.

1. *The Asserted Claims*

a. #293 Patent, Claim 5

1. Claim 5 of the #293 Patent reads: The compound or salt of claim 1, wherein the compound is selected from the group consisting of:



or an L-malate salt thereof.

b. #293 Patent, Claim 21

2. Claim 21 of the #293 Patent reads: A pharmaceutical composition, comprising a compound or salt of claim 5 and, a pharmaceutically acceptable carrier or excipient.

c. #905 Patent, Claim 1

3. Claim 1 of the #905 Patent reads: A compound that is the L-malate salt of 5–(5–fluoro–2–oxo–1,2–dihydroindol–3–ylidenemethyl)–2,4–dimethyl–1H–pyrrole–3–carboxylic acid (2–diethylaminoethyl)amide.

***466** *d. #905 Patent, Claim 2*

4. Claim 2 of the #905 Patent reads: A pharmaceutical composition comprising the compound of claim 1 and a pharmaceutically acceptable carrier or excipient.

D. Sutent® and Mylan's ANDA

1. The #293 and #905 patents cover, *inter alia,* the compound sunitinib malate. Pfizer sells pharmaceutical capsules containing sunitinib malate under the trade name Sutent®, pursuant to a New Drug Application that has been approved by the United States Food and Drug Administration ("FDA"). Sutent® is indicated for the treatment of "advanced renal cell carcinoma," "gastrointestinal stromal tumor after disease progression on or intolerance to imatinib mesylate," and "progressive, well-differentiated pancreatic neuroendocrine tumors in patients with unresectable locally advanced or metastatic disease." The FDA has approved Sutent® in 12.5 mg, 25 mg, 37.5 mg, and 50 mg dosage strengths.

2. Mylan has submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 201–275, seeking approval to sell generic versions of drug products containing sunitinib malate in 12.5 mg, 25 mg, 37.5, and 50 mg dosage strengths ("Mylan's ANDA Products"). ANDA No. 201–275 contains certifications pursuant to

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