IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, et al.,	:	**CIVIL ACTION**
Plaintiffs,	:	
v.	:	**NO. 15-902**
AUROBINDO PHARMA LIMITED, et al.,	:	
Defendants.	:	

Findings of Fact, Conclusions of Law and Verdict

STENGEL, C.J.[1] **July 13, 2018**

I. Introduction

This is a consolidated patent infringement action arising under the Hatch-Waxman Act. The plaintiffs, Bayer Intellectual Property GMBH, Bayer Pharma AG, and Janssen Pharmaceuticals, Inc. (collectively "Bayer") allege infringement of claim 16 of U.S. Patent No. 7,157,456 (the "'456 patent"), which claims the compound rivaroxaban. The parties concede infringement. Defendants, Mylan Pharmaceuticals Inc. and Sigmapharm Laboratories, LLC submit that the patent is invalid as obvious. I held a four-day bench trial beginning on March 5, 2018 through March 9, 2018.[2]

Presently before me are the parties' proposed findings of fact and conclusions of law. Pursuan t to Federal Rule of Civil Procedure 52(a), having considered the entire

[1] Chief Judge Lawrence F. Stengel of the Eastern District of Pennsylvania is sitting by designation in this case filed in Delaware District Court pursuant to the provisions of 28 U.S.C. § 292(b), and by Order of Chief Judge D. Brooks Smith of the Third Circuit. (Doc. No. 268.)
[2] The Court was closed due to inclement weather on March 7, 2018.

record and the relevant law, I find that the asserted claim of the ’456 patent is not invalid due to obviousness. The findings of fact and conclusions of law are set forth in further detail below.

II. Procedural History

On October 9, 2015, plaintiffs filed a complaint alleging infringement of the ’456, ’860, and ’339 patents. (Doc. No. 1.) Sigmapharm filed its answer on October 30, 2015, alleging that the patents were invalid. (Doc. No. 26.) On January 19, 2016, Mylan filed its answer, also asserting as an affirmative defense that the patents were invalid. (Doc. No. 66.)

The parties filed separate stipulations stating that the products that are the subject of defendants’ ANDAs infringe any valid claims of the ’456, ’860, and ’339 patents, including claim 16 of the ’456 patent. (Doc. Nos. 232, 236.) Plaintiffs later notified defendants that, for purposes of narrowing the issues for trial, they would only assert claim 16 of the ’456 patent. (Doc. No. 286 at ¶ 8; Doc. No. 287 at ¶ 15.)

Beginning on March 5, 2018, I held a four-day bench trial. The parties submitted post-trial briefing and on April 25, 2018 I heard closing arguments.

III. Findings of Fact

A. The parties

1. The Bayer plaintiffs are corporations organized and existing under the laws of the Federal Republic of Germany. (Doc. No. 286-1, Ex. 6, ¶¶ 6-7.)

2. Janssen is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania. (Id. at ¶ 8.)

3. Mylan is a corporation organized and existing under the laws of the State of West Virginia. (Id. at ¶ 18.)

4. Sigmapharm is a limited liability company organized and existing under the laws of the Commonwealth of Pennsylvania. (Id. at ¶ 14.)

5. Janssen is the holder of approved New Drug Application No. 22406 for Xarelto® (rivaroxaban). (Id. at ¶ 12.)

6. Xarelto® is a factor Xa inhibitor which is indicated to (1) reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (2) for the treatment of deep vein thrombosis (DVT); (3) for the treatment of pulmonary embolism (PE); (4) for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; and (5) for the prophylaxis (prevention) of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. (Id. at ¶ 10.)

B. The patent-in suit

7. The ’456 patent is entitled “Substituted Oxazolidinones and Their Use in the Field of Blood Coagulation.” (Id. at ¶ 1.)

8. The named investors are Alexander Straub, Thomas Lampe, Jens Pohlmann, Susanne Roehrig, Elisabeth Perzborn, Karl-Heinz Schlemmer, and Joseph Pernerstorfer. (Id.)

9. The patent was issued on January 2, 2007, expires on August 28, 2024, and is currently assigned to Bayer Intellectual Property GmbH. (Id. at ¶¶ 1, 2.) The priority date for the patent is December 24, 1999. (3/5/18 a.m. Tr. 33:12-19.)

C. ANDA No. 208546

10. Sigmapharm submitted Abbreviated New Drug Application ("ANDA") No. 208546 to the FDA seeking approval of its proposed rivaroxaban tablets under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act ("Paragraph IV Certification") that the claims of the '456 patent and U.S. patent Nos. 7,585,860 (the "'860 patent") and 7,592,339 (the "'339 patent") were invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Sigmapharm's proposed rivaroxaban tablets. (Doc. No. 286-1, Ex. 6, ¶ 16.)

11. By letter dated August 31, 2015, Sigmapharm notified plaintiffs that it submitted ANDA No. 208546. (Id. at ¶ 15.)

D. ANDA No. 208561

12. Mylan submitted ANDA No. 208561 also seeking approval of its proposed rivaroxaban tablets contained in a Paragraph IV Certification that the '456, '860, and '339 patents were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of Mylan's proposed rivaroxaban tablets. (Id. at ¶ 20.)

13. On September 15, 2015, Mylan notified plaintiffs that it submitted ANDA No. 208561. (Id. at ¶ 19.)

E. Expert Witnesses

14. Dr. Steven Brickner, defendants' medicinal chemistry expert, received a Ph.D.

in organic chemistry from Cornell University; worked in the pharmaceutical industry as a medicinal chemist for 27 years, and has another nine years' experience as a medicinal chemistry consultant and is a named inventor on thirty (30) U.S. Patents and Patent Applications. (Defs. FF. ¶ 12 (citing 3/5/18 a.m. Tr. 9:20-11:11; 12:14-13:7; DTX-1266).) Dr. Brickner is accredited with discovering linezolid. (Id. (citing 3/5/18 a.m. Tr. 10:12-11:13).)

15. Dr. Spada, plaintiffs' medicinal chemistry expert, was the medicinal chemistry head of a factor Xa inhibitor program from 1993 through 1999; he is the co-author/inventor on numerous publications and patent applications in the factor Xa space, including the Ewing II article, discussed infra; and was familiar with the factor Xa field in December of 1999 including by reviewing the literature and attending conferences. (Pltffs. FF. ¶ 16 (citing 3/8/18 a.m. Tr. 57:2-59:1; PTX-9).)

16. Although both Dr. Spada and Br. Brickner are experienced medicinal chemists, I find that Dr. Spada's testimony is credible and reliable and it informs my obviousness analysis.[3]

F. The Person of Ordinary Skill in the Art

17. The POSA pertaining to the '456 patent as of December 24, 1999 (the priority date), is defined as follows,

> A scientist with a Ph.D. in organic chemistry, or an equivalent discipline, with approximately seven (7) years of experience with the synthesis of organic

[3] In reaching my conclusions, I also considered the expert testimony of Dr. Neil Doherty, III and Ivan Hofmann on behalf of the defendants. Likewise, I considered the testimony of Dr. George Zhanel, Dr. Jeffrey Olin, and Dr. Christopher Vellturo on behalf of plaintiffs. Finally, I considered the testimony of all fact witnesses.

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