IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 17-648 (RGA)
SIGMAPHARM LABORATORIES, LLC,	)	
Defendant.	)	

PLAINTIFFS' ANSWER TO COUNTERCLAIMS

Plaintiffs Bayer Intellectual Property GmbH ("BIP"), Bayer AG (Bayer AG and BIP are collectively referred to herein as "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Plaintiffs" or "Counterclaim Defendants"), by their attorneys, hereby answer the counterclaims of Defendant and Counterclaim Plaintiff Sigmapharm Laboratories, LLC ("Sigmapharm"), using the paragraph numbers of Sigmapharm's Answer, Affirmative Defenses and Counterclaims, D.I. 11, as follows:

Plaintiffs reassert as if fully set forth each of the paragraphs of Plaintiffs' Complaint.

49. On information and belief, admitted that Sigmapharm is a limited liability company organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 3375 Progress Drive, Bensalem, Pennsylvania 19020.

50. Admitted that Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim am Rhein, Germany.

51. Admitted that Bayer Pharma AG—which is not a party to this case—is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

52. Admitted that Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

53. The allegations in paragraph 53 are legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest personal jurisdiction for purposes of this action.

54. The allegations in paragraph 54 are legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest subject matter jurisdiction.

55. The allegations in paragraph 55 are legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest venue for purposes of this action.

56. The allegations in the first sentence of paragraph 56 are legal conclusions to which no response is required. To the extent a response is required, admitted that there is an actual case or controversy between Sigmapharm and Plaintiffs with respect to liability for infringement of U.S. Patent No. 9,539,218 ("the '218 patent"), but denied that Sigmapharm is entitled to any of the relief that it seeks. Admitted that Plaintiffs filed this action against Sigmapharm on the basis of Sigmapharm's submission of ANDA No. 208546.

57. The allegations in paragraph 57 are legal conclusions to which no response is required. To the extent a response is required, admitted that there is an actual case or

controversy between Sigmapharm and Plaintiffs with respect to liability for infringement of the '218 patent, but denied that Sigmapharm is entitled to any of the relief that it seeks. Further denied that Sigmapharm has stated a claim under 35 U.S.C. § 271(e)(5).

58. The allegations in paragraph 58 characterize federal statutes, which speak for themselves.

59. The allegations in paragraph 59 characterize federal statutes and regulations, which speak for themselves.

60. The allegations in paragraph 60 characterize a federal statute, which speaks for itself.

61. Denied.

62. Admitted that the Drug Price Competition and Patent Term Restoration Act of 1984 affected a change in the law regarding FDA procedures. Otherwise, denied.

63. Admitted that the Drug Price Competition and Patent Restoration Act of 1984 was enacted in 1984. The second and third sentences of paragraph 63 characterize federal statutes, which speak for themselves.

64. The allegations in paragraph 64 characterize federal statutes and regulations, which speak for themselves.

65. The allegations in paragraph 65 characterize a federal statute, which speaks for itself.

66. The allegations in paragraph 66 characterize a federal statute, which speaks for itself.

67. The allegations in paragraph 67 characterize federal statutes, which speak for themselves.

68. The allegations in paragraph 68 characterize a federal statute, which speaks for itself. Admitted that Plaintiffs have properly filed an action against Sigmapharm in this District for infringement of the '218 patent, and that Plaintiffs' Complaint speaks for itself. Denied that Plaintiffs' action against Sigmapharm lacks merit.

69. The allegations in paragraph 69 characterize a federal statute, which speaks for itself.

70. Admitted that the '218 patent issued on January 10, 2017 and that the '218 patent is entitled "Prevention and Treatment of Thromboembolic Disorders." Admitted that Bayer Intellectual Property GmbH owns and is the assignee of the '218 patent. Admitted that Bayer AG is an exclusive licensee under the '218 patent. Admitted that Janssen is an exclusive sublicensee under the '218 patent.

71. Admitted that Janssen Pharmaceuticals, Inc. is the holder of New Drug Application No. 022406 for XARELTO® rivaroxaban 10 mg, 15 mg and 20 mg tablets. Admitted that Janssen sells XARELTO® rivaroxaban 10 mg, 15 mg and 20 mg tablets in the United States.

72. Admitted.

73. Upon information and belief, admitted.

74. Admitted that the '218 patent is properly listed in the Orange Book for XARELTO®. Further admitted, on information and belief, that Sigmapharm's ANDA for generic versions of XARELTO® contained or was updated to contain a paragraph IV certification with respect to the '218 patent. Denied that the '218 patent is invalid or unenforceable. Denied that the use of Sigmapharm's proposed generic version of XARELTO® in accordance with its proposed labeling would not infringe the '218 patent.

75. Admitted that Sigmapharm sent a Notice Letter, which speaks for itself. Denied that the '218 patent is invalid or unenforceable. Denied that the use of Sigmapharm's proposed generic version of XARELTO® in accordance with its proposed labeling would not infringe the '218 patent. Plaintiffs deny the remaining allegations in paragraph 75.

76. Admitted that Sigmapharm sent a Notice Letter, which speaks for itself. Denied that the '218 patent is invalid or unenforceable. Denied that the use of Sigmapharm's proposed generic version of XARELTO® in accordance with its proposed labeling would not infringe the '218 patent. Plaintiffs deny the remaining allegations in paragraph 76.

77. Admitted that on May 26, 2017, Bayer and Janssen sued Sigmapharm for infringement of the '218 patent.

78. The allegations in paragraph 78 are legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that they have properly filed a Complaint to enforce their patent rights in accordance with the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 and associated regulations. Plaintiffs deny the remaining allegations in paragraph 78.

79. Denied.

80. Denied.

81. Denied.

82. Admitted that there is an actual case or controversy between Sigmapharm and Plaintiffs with respect to liability for infringement of the '218 patent, and that it is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment in favor of Plaintiffs, but denied that Sigmapharm is entitled to any of the relief that it seeks.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.