IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA AT CLARKSBURG

BAUSCH HEALTH IRELAND LIMITED and SALIX PHARMACEUTICALS, INC.,

Plaintiffs,

v.

Civil Action No. 1:22-cv-00020 (Kleeh)

MYLAN LABORATORIES LTD.; AGILA SPECIALTIES INC.; MYLAN API US LLC; MYLAN INC.; VIATRIS INC.; and MYLAN PHARMACEUTICALS INC.,

Defendants.

DEFENDANT MYLAN PHARMACEUTICALS INC.'S FIRST SET OF REQUESTS FOR PRODUCTION TO PLAINTIFFS (Nos. 1-132)

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Defendant Mylan Pharmaceuticals Inc. ("MPI" or "Defendant") requests that Plaintiffs Bausch Health Ireland Limited ("Bausch") and Salix Pharmaceuticals, Inc. ("Salix") (collectively "Plaintiffs") serve written responses to the following Requests and produce the requested documents and other items within thirty (30) days of service, at the offices of Wilson Sonsini Goodrich & Rosati, Professional Corporation, 900 South Capital of Texas Highway, Las Cimas IV, Fifth Floor, Austin, TX 78746, or at such other location and time as the parties may agree, and permit the inspection and copying of the following documents and other tangible items that are in Ravgen's possession, custody, or control. These Requests are continuing in nature and require supplemental production in accordance with the Federal Rules of Civil Procedure.



DEFINITIONS

- 1. "Plaintiffs" and "You" means individually and collectively, Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. its officers, directors, current and former employees, counsel, agents, consultants, representatives, and any other Persons acting on behalf of any of the foregoing, including affiliates, parents, divisions, joint ventures, licensees, franchisees, assignees, predecessors and successors in interest, and any other legal entities, whether foreign or domestic, that are owned or controlled by Bausch and/or Salix, any entity owned in whole or in part by, affiliated with, or controlled in whole or in part by Bausch and/or Salix, and entities acquired through merger or acquisition.
- 2. "Defendant" means Mylan Pharmaceuticals Inc., and its officers, directors, employees, agents, attorneys, parents, subsidiaries, affiliated or predecessor corporations, and any other Person or entity acting on its behalf or subject to its control.
- 3. "Synergy" means Synergy Pharmaceuticals Inc., and its officers, directors, employees, agents, attorneys, parents, subsidiaries, affiliated or predecessor corporations, and any other Person or entity acting on its behalf or subject to its control.
- 4. "Callisto" means Callisto Pharmaceuticals Inc., and its officers, directors, employees, agents, attorneys, parents, subsidiaries, affiliated or predecessor corporations, and any other Person or entity acting on its behalf or subject to its control.
- 5. "AmbioPharm" means AmbioPharm, Inc., and its officers, directors, employees, agents, attorneys, parents, subsidiaries, affiliated or predecessor corporations, and any other Person or entity acting on its behalf or subject to its control.



- 6. The term "Patents-in-Suit" refers to: United States Patent Nos. 7,041,786 ("the '786 patent"), 9,610,321 ("the '321 patent"), 9,616,097 ("the '097 patent"), 9,919,024 ("the '024 patent"), 9,925,231 ("the '231 patent") and 10,011,637 ("the '637 patent").
- 7. The terms "Related Patent Families" and "Related Patents" refer to the Patents-in-Suit and all underlying patents and patent applications, including published and unpublished applications, abandoned applications and patents, parents, continuations, continuations-in-part, divisionals, reissues, foreign counterparts, and any other patents or patent applications claiming priority or reciting a relation to the Patents-in-Suit, claiming priority to any application to which one or more of the Patents-in-Suit claims priority, or to which the Patents-in-Suit claim priority, whether directly or indirectly, or recite a relation.
- 8. The term "MSN Litigation" refers to the matter, *Bausch Health Ireland Limited* and Salix Pharmaceuticals, Inc. v. MSN Private Ltd. and MSN Pharmaceuticals Inc., Case No. 21-10057 (D. NJ) filed on April 22, 2021.
- 9. The term "Shailubhai" means Kumwar Shailubhai, a named inventor of the '786,'097, '024, '231, and '637 patents, as well as any of his employees, affiliates, attorneys, or agents.
- 10. The term "Nikiforovich" means Gregory Nikiforovich, a named inventor of the '786 patent, as well as any of his employees, affiliates, attorneys, or agents.
- 11. The term "Jacob" means Gary S. Jacob, a named inventor of the '786 patent, as well as any of his employees, affiliates, attorneys, or agents.
- 12. The term "Comiskey" means Stephen Comiskey, a named inventor of the '321, '097, '024, '231, and '637 patents, as well as any of his employees, affiliates, attorneys, or agents.



- 13. The term "Feng" means Ron Feng, a named inventor of the '321, '097, '024, '231, and '637 patents, as well as any of his employees, affiliates, attorneys, or agents.
- 14. The term "Foss" means John Foss, a named inventor of the '321, '097, '024, and '231 patents, as well as any of his employees, affiliates, attorneys, or agents.
- 15. The term "Bai" means Juncai Bai, a named inventor of the '637 patent, as well as any of his employees, affiliates, attorneys, or agents.
- 16. The term "R. Zhang" means Ruoping Zhang, a named inventor of the '637 patent, as well as any of his employees, affiliates, attorneys, or agents.
- 17. The term "Jia" means Jun Jia, a named inventor of the '637 patent, as well as any of his employees, affiliates, attorneys, or agents.
- 18. The term "Zhou" means Junfeng Zhou, a named inventor of the '637 patent, as well as any of his employees, affiliates, attorneys, or agents.
- 19. The term "Zhao" means Qiao Zhao, a named inventor of the '637 patent, as well as any of his employees, affiliates, attorneys, or agents.
- 20. The term "G. Zhang" means Guoqing Zhang, a named inventor of the '637 patent, as well as any of his employees, affiliates, attorneys, or agents.
 - 21. "FDA" means the United States Food & Drug Administration.
 - 22. "NDA" means New Drug Application.
 - 23. "IND Application" means Investigational New Drug Application.
- 24. "Communication" means any transmission of information between two or more persons, including information transmitted by way of telephone conversations, letters, faxes, email, computer links, written memorandums or other documents, bulletin board posting, and face-to-face conversations.



- 25. The term "USPTO" means the United States Patent and Trademark Office.
- 26. The term "The Comiskey Declaration" refers to the declaration of Stephen Comiskey signed on February 18, 2015 and filed with the United States Patent Office under 37 C.F.R. § 1.132 during the prosecution of United States Patent Application No. 13/421,769, which issued as U.S. Patent No. 9,616,097.
- 27. The term "The Second Comiskey Declaration" refers to the declaration of Stephen Comiskey signed on September 06, 2016 and filed with the United States Patent Office under 37 C.F.R. § 1.132 during the prosecution of United States Patent Application No. 14/845,644, which issued as U.S. Patent No. 9,610,321.
- 28. The term "Avicel PH112" refers to a proprietary microcrystalline cellulose manufactured by Dupont and is an ingredient used in the studies that are the subject of both Comiskey Declarations identified as "a low-moisture carrier."
- 29. The term "Avicel PH102" refers to a proprietary microcrystalline cellulose manufactured by Dupont and is an ingredient used in the studies that are the subject of both Comiskey Declarations identified as "a regular grade carrier."
- 30. The term "Bai reference" refers to the International Application Published under the Patent Cooperation Treaty as WO 2012/118973 A2 on September 7, 2012, and any applications claiming priority to US Provisional Application No. 61/447,891.
- 31. The term "Secondary Considerations" or "Objective Indicia" refers to secondary considerations of nonobviousness as the term is used in *Graham v. John Deere Co.*, 338 U.S. 1, 18 (1966), and subsequently developed cases.
- 32. The terms "License" and "Licensee," as used herein, shall include the meaning of sublicense and sublicensee, and any further subordinations thereto.



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