

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

SANOFI-AVENTIS U.S. LLC,  
SANOFI-AVENTIS DEUTSCHLAND  
GMBH, and SANOFI WINTHROP  
INDUSTRIE,

Plaintiffs,

v.

MYLAN N.V., MYLAN GMBH, MYLAN  
INC., and MYLAN PHARMACEUTICALS  
INC.,

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR  
PATENT INFRINGEMENT**

*Electronically Filed*

Plaintiffs Sanofi-Aventis U.S. LLC (“Sanofi U.S.”), Sanofi-Aventis Deutschland GmbH (“Sanofi GmbH”), and Sanofi Winthrop Industrie (“SWIND”) (collectively, “Plaintiffs” or “Sanofi”), by and through their attorneys, for their Complaint against Mylan N.V., Mylan GmbH, Mylan Inc., and Mylan Pharmaceuticals Inc. (“Mylan Pharma”) (collectively, “Mylan” or “Defendants”), hereby allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* arising from Mylan’s filing of New Drug Application (“NDA”) No. 210605 with the United States Food and Drug Administration (“FDA”), seeking approval to commercially market Mylan’s proposed copies of Sanofi’s Lantus<sup>®</sup> and Lantus<sup>®</sup> SoloSTAR<sup>®</sup> drug products (“Proposed Products”) prior to the expiration of United States Patent Nos. 7,476,652 (“the ’652 patent”), 7,713,930 (“the ’930 patent”), 7,918,833 (“the ’833 patent”), 8,512,297 (“the ’297 patent”), 8,556,864 (“the ’864 patent”), 8,603,044 (“the ’044 patent”), 8,679,069 (“the ’069 patent”), 8,992,486 (“the ’486 patent”), 9,011,391 (“the ’391 patent”),

9,233,211 (“the ’211 patent”), 9,408,979 (“the ’979 patent”), 9,526,844 (“the ’844 patent”), 9,533,105 (“the ’105 patent”), 9,561,331 (“the ’331 patent”), 9,604,008 (“the ’008 patent”), 9,604,009 (“the ’009 patent”), 9,610,409 (“the ’409 patent”), and 9,623,189 (“the ’189 patent”), (collectively, “the patents-in-suit”), which cover Lantus<sup>®</sup> and/or Lantus<sup>®</sup> SoloSTAR<sup>®</sup>.

### **THE PARTIES**

2. Plaintiff Sanofi U.S. is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Plaintiff Sanofi GmbH is a German corporation with its principal place of business located at Industriepark Hoechst, Frankfurt Am Main, Germany D-65926.

4. Plaintiff SWIND is a French corporation with its principal place of business located at 20 Avenue Raymond Aron, 92160 Antony, France.

5. On information and belief, Defendant Mylan N.V. is a company organized and existing under the laws of the Netherlands, with its global headquarters and principal offices located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. On information and belief, Mylan N.V. is in the business of, among other things, marketing and selling follow-on versions of branded pharmaceutical products for the United States market, alone and/or through its subsidiaries, agents, and affiliates. On information and belief, Mylan N.V. is the ultimate corporate parent of Mylan GmbH, Mylan Inc., and Mylan Pharma.

6. On information and belief, Mylan N.V. conducts business operations, directly or through its subsidiaries, agents and/or affiliates, in the State of New Jersey.

7. On information and belief, Defendant Mylan GmbH is a company organized and existing under the laws of Switzerland, with a principal place of business at Thurgauerstrasse 40, CH-8050 Zurich, Switzerland. On information and belief, Mylan GmbH is in the business of,

among other things, marketing and selling follow-on versions of branded pharmaceutical products for the United States market, alone and/or through its subsidiaries, agents, and affiliates. On information and belief, Mylan GmbH is a wholly-owned subsidiary of Mylan N.V., is controlled by Mylan N.V., and is an agent and/or affiliate of Mylan Pharma and Mylan Inc.

8. On information and belief, Mylan GmbH conducts business operations, directly or through its subsidiaries, agents and/or affiliates, in the State of New Jersey.

9. On information and belief, Defendant Mylan Inc. is a company organized and existing under the laws of the Commonwealth of Pennsylvania with its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Inc. is in the business of, among other things, marketing and selling follow-on versions of branded pharmaceutical products for the United States market, alone and/or through its subsidiaries, agents, and affiliates. Mylan Inc. is a wholly-owned subsidiary of Mylan N.V., is controlled by Mylan N.V., and is an agent and/or affiliate of Mylan GmbH and Mylan Pharma.

10. On information and belief, Mylan Inc. conducts business operations, directly or through its subsidiaries, agents and/or affiliates, in the State of New Jersey.

11. On information and belief, Defendant Mylan Pharma is a company organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505-4310. On information and belief, Mylan Pharma is in the business of manufacturing and selling follow-on versions of branded pharmaceutical products for the United States market alone and/or through its subsidiaries, agents, and affiliates. On information and belief, Mylan Pharma is wholly-owned subsidiary of Mylan Inc., is controlled by Mylan Inc., and is an agent and/or affiliate of Mylan GmbH.

12. On information and belief, Mylan Pharma conducts business operations, directly or through its subsidiaries, agents and/or affiliates, in the State of New Jersey.

13. On information and belief, Mylan N.V. and Mylan GmbH operate in the United States and in the State of New Jersey through Mylan Inc. and Mylan Pharma. On information and belief, Mylan Inc. and Mylan Pharma are United States agents for Mylan GmbH and Mylan N.V. for purposes including, but not limited to, corresponding with the Food and Drug Administration (“FDA”).

14. For example, on information and belief, at least Mylan Inc. and Mylan GmbH worked in concert to prepare and file NDA No. 210605 by conducting a “Non-inferiority Study to Compare the Efficacy and Safety of Mylan’s Insulin Glargine With Lantus® in Type 2 Diabetes Mellitus Patients” and a “Non-inferiority Study to Compare the Efficacy and Safety of Mylan’s Insulin Glargine With Lantus® in Type 1 Diabetes Mellitus Patients.” See Exhibits S and T. Mylan Inc. is listed as the Sponsor and Responsible Party on these studies and Mylan GmbH is listed as Collaborator. *Id.*

15. On June 5, 2017, Mylan Pharma filed petitions for *Inter Partes* Review of the ’652 and ’930 patents. *Mylan Pharms. Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2017-01526, Paper 2 (P.T.A.B. June 5, 2017); *Mylan Pharms. Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2017-01528, Paper 2 (P.T.A.B. June 5, 2017). In accordance with 37 C.F.R. § 42.8(b)(1), Mylan identified Mylan Pharma, Mylan Inc., Mylan GmbH, and Mylan N.V., among others, as real parties-in-interest. *Id.* at 2.

16. That Mylan Pharma, Mylan Inc., Mylan GmbH, and Mylan N.V. are real parties-in-interest to the petitions filed in IPR2017-01526 and IPR2017-01528 indicates that all four Mylan entities stand to benefit from approval of NDA No. 210605.

17. On information and belief, the acts of Mylan GmbH complained of herein were done at the direction and/or, with the authorization of, and/or with the cooperation, participation, and assistance of Mylan N.V., Mylan Inc., and Mylan Pharma.

18. On information and belief, Mylan Inc. is the registrant organization for the website mylan.com. *See* Exhibit U. Mylan Inc. has used Mylan Pharma's address as the registrant address for the website mylan.com, further indicating that Defendants operate as one entity. *See id.*

19. On information and belief, Mylan holds itself out as having contacts with the State of New Jersey by stating on its website that it aims to provide a "Better Health for a Better New Jersey." *See* Exhibit V. Specifically, the website reports that in "[i]n 2016, Mylan generics saved New Jersey \$700 million." *Id.* Further, it states that "Mylan is the leader in the fight against many of New Jersey's most prevalent diseases." *Id.*

20. On information and belief, Mylan holds itself out as having contacts with the State of New Jersey by stating in its website that:

Mylan's commitment to expanding access to medicine extends beyond just offering products. Take potentially life-threatening allergic reactions, or anaphylaxis. These reactions can occur quickly and without warning. Of the nearly 8.9 million people in New Jersey, approximately 178,000 may be at risk.

Exhibit W.

21. On information and belief, Mylan holds itself out as having contacts with the State of New Jersey by stating in its website that:

Over the past five years, 54,424 free epinephrine auto-injectors have been provided to 3,577 schools in New Jersey, approximately 81% of the state's schools. Since the program began in 2012, epinephrine auto-injectors provided through the EpiPen4Schools program have been used 109 times in New Jersey to treat an anaphylactic reaction in the school setting.

*Id.* at 2.

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