

March 18, 2021

**HIGHLY CONFIDENTIAL**

**VIA FEDERAL EXPRESS  
RETURN RECEIPT REQUESTED**

Salix Pharmaceuticals, Inc.  
400 Somerset Corporate Blvd.  
Bridgewater, NJ 08807

Synergy Pharmaceuticals Inc.  
420 Lexington Avenue  
Suite 2012  
New York, NY 10170

Bausch Health Ireland Limited  
3013 Lake Drive  
Citywest Business Campus  
Dublin 24, Ireland

**Re: Plecanatide Tablets, 3mg (Trulance<sup>®</sup>, chronic idiopathic constipation (CIC)  
and irritable bowel syndrome with constipation (IBS-C))**

**Dosage Form: Tablet**

**Dosage Strength: 3mg**

**Route of Administration: Oral**

**United States Patent No. 7,041,786; United States Patent No. 9,610,321;**

**United States Patent No. 9,616,097; United States Patent No. 9,919,024;**

**United States Patent No. 9,925,231; United States Patent No. 10,011,637**

**Notice of Paragraph IV Certification**

To Whom It May Concern:

This is a notice-of-certification letter on behalf of Mylan Pharmaceuticals Inc., a Viatrix Company ("Mylan"), pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act ("the Act") and §§ 314.94 and 314.95 of Title 21 of the Code of Federal Regulations.

under § 505(j) of the Act contains any required bioavailability or bioequivalence data or information.

2. The ANDA number is 215686.
3. Mylan has received FDA's Paragraph IV acknowledgment letter for ANDA No. 215686.
4. The established name of Mylan's proposed drug is Plecanatide Tablets, 3mg. Salix Pharmaceuticals Inc. ("Salix") holds an NDA on marketed products that contain the active ingredient plecanatide in 3mg dosage strength intended for oral administration under the brand name Trulance®.
5. The ANDA indicates that Mylan seeks to obtain approval for the drug product before the expiration dates for 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") which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for Plecanatide (Trulance®) Tablet 3mg.

<u>Patent Number</u>	<u>Orange Book Expiration Date<sup>1</sup></u>
7,041,786 (the "'786 Patent")	January 30, 2028
9,610,321 (the "'321 Patent")	September 15, 2031
9,616,097 (the "'097 Patent")	August 20, 2032
9,919,024 (the "'024 Patent")	September 15, 2031
9,925,231 (the "'231 Patent")	September 15, 2031
10,011,637 (the "'637 Patent")	June 5, 2034

6. A detailed statement of the present factual and legal bases of Mylan's belief that the '786 Patent; the '321 Patent; the '097 Patent; the '024 Patent; the '231 Patent; and the '637

<sup>1</sup> The expiration dates of the patents are based upon information available in the FDA Orange Book. See FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

7. An Offer of Confidential Access is enclosed.

8. Wilson Sonsini Goodrich & Rosati P.C. is authorized to accept service of process for Mylan, solely relating to ANDA No. 215686. Please direct any correspondence in this regard to my attention.

9. **Anticompetitive Behavior Warning.** It is an antitrust violation to assert any patent known not to be infringed, or known not to be valid. *See Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861 (Fed. Cir. 1985); *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986 (9th Cir. 1979). If Salix launches any patent infringement lawsuit, either now or later, Mylan may pursue the appropriate remedies against Salix, including seeking fees, costs, and sanctions for potential violations of Rule 11 of the Federal Rules of Civil Procedure, exceptional case and frivolous suit statutes under the patent laws, and for violations of the antitrust laws and/or other laws, plus any remedy the court deems fit to award.

The information in this letter and its attachments is supplied for the sole purpose of complying with the above-referenced statutes and regulations. Neither Mylan nor its attorneys waive any attorney-client privilege or work-product immunity concerning the subject matter of this communication.

**Reservation of Legal Right**

Mylan reserves the right to assert the same, similar, different or new theories of non-infringement, invalidity and/or unenforceability and nothing in this Notice Letter or Detailed Statement shall be construed as to limit Mylan's right to make any allegation in any litigation regarding any issue.

Sincerely,

WILSON SON SINI GOODRICH & ROSATI  
Professional Corporation



Nicole W. Stafford

Encl.: Detailed Statement of the Factual and Legal Bases for Mylan's Paragraph IV Certification Concerning with respect to United States Patent Nos. 7,041,786; 9,610,321; 9,616,097; 9,919,024; 9,925,231; and 10,011,637.



The manufacture, use, offer to sell, or sale of Mylan's proposed Plecanatide Tablets, 3mg will not infringe any valid and enforceable claim of U.S. 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").

## I. APPLICABLE LEGAL PRINCIPLES

### A. Burdens and Presumption

Each claim of a patent issued by the U.S. Patent and Trademark Office ("USPTO") is presumed to be valid; this presumption is independent of the validity of other claims. *See Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 95 (2011) (citing 35 U.S.C. § 282 (2000)). A party may overcome this presumption by presenting clear and convincing evidence. *Id.*

Although prior art not presented during prosecution "may facilitate meeting the challenger's ability to meet the burden of proof on invalidity," the burden of presenting clear and convincing evidence by the challenger remains intact and does not change. *Atlas Powder Co. v. El Du Pont De Nemours & Co.*, 750 F. 2d 1569, 1573 (Fed. Cir. 1984); *see also i4i*, 564 U.S. at 110-12 (rejecting a fluctuating standard of proof, propounded by the patent owner, by which a preponderance of the evidence standard would apply for prior art not considered by the USPTO during prosecution of the patent application); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1535 (Fed. Cir. 1983). Proving invalidity, however, is not limited to prior art not presented during prosecution, and a patent may also be found invalid based upon prior art considered by the examiner. Deference to the examiner is provided through the presumption of validity that is accorded to issued patents under 35 U.S.C. § 282. *E.g., Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1329 (Fed. Cir. 2000). Thus, a trial court is free to come to a different conclusion of patentability from the USPTO on the basis of clear and convincing evidence presented to the court. *Id.*; *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1245 (Fed. Cir. 2003).

### B. Invalidity - Obviousness

Even if no single reference discloses the claimed invention, a claim may still be found invalid by reason of obviousness. *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1084 (Fed. Cir. 1985).

"Obviousness under 35 U.S.C. § 103 is a mixed question of fact and law." *ABT Systems, LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1354 (Fed. Cir. 2015). "While a jury may render a decision on a question of obviousness when it is considering any underlying fact questions, obviousness is ultimately a question of law." *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554

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