below. Write ''In the Matter of Teva Pharmaceutical Industries Ltd. and Allergan plc, File No. 151–0196, C–4589—Consent Agreement'' on your comment and file your comment online at :// . / / by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''In the Matter of Teva Pharmaceutical Industries Ltd. and Allergan plc, File No. 151–0196, C–4589—Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. FTC Rule 4.9(c), 16 CFR 4.9(c).

U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening current or future competition in pharmaceutical markets for one or more strengths of ninety-four pharmaceutical products in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

I. The Products and Structure of the Markets

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Generic drugs are chemically and therapeutically equivalent to branded drugs. When a physician prescribes a particular branded drug, a pharmacy may only dispense that branded drug or its generic equivalent, which is ''AB-rated'' to the branded product. State laws permit or require pharmacies to automatically substitute the generic equivalent for the prescribed branded drug unless a physician expressly states not to do so.

The 1984 Hatch-Waxman Act provides the statutory framework for the Food and Drug Administration (''FDA'') to approve generic drugs. Under Hatch-Waxman, a generic drug manufacturer can rely on an already-approved branded drug's safety and efficacy data in its own application—called an Abbreviated New Drug Application (''ANDA'')—to the FDA, substantially lowering the research and development cost of the generic drug. Upon FDA approval, a generic drug typically launches at a discount to the branded drug's price. When there is only one generic drug on the market, the branded drug usually competes with the generic drug on price, either directly or through an authorized generic version. As subsequent generic drugs launch, a generic-only market typically forms, with competition among generics driving pricing. When multiple generic drugs are available, customers usually substitute between the generics only—not the branded drug—and solicit bids exclusively from generic drug suppliers.

Teva's proposed acquisition of Allergan's generic pharmaceutical business will lessen current or future competition by reducing the number of current or future suppliers in the pharmaceutical markets for one or more strengths of seventy-nine pharmaceutical products. Those markets fall into three categories: (1) Current competition between Teva and Allergan; (2) future competition between Teva and Allergan in an existing generic market; and (3) future competition between Teva and Allergan in a future generic market (*e.g.,* the generic market has not yet formed and only the branded drug is on the market). Absent a remedy, the proposed acquisition would reduce the number of suppliers in each market as indicated below.

- Current Competition Between Teva and Allergan, 2-to-1 Supplier Consolidation

Æ Armodafinil Oral Tablet, 200 mg
Æ Desogestrel/Ethinyl Estradiol Oral Tablet, 0.025/0.1 mg then 0.025/0.125 mg then 0.025/0.15 mg (AB-rated to Cyclessa)
Æ Estazolam Oral Tablet, 1 mg
Æ Estazolam Oral Tablet, 2 mg
Æ Ethinyl Estradiol/Ethynodiol Diacetate Oral Tablet, 0.035/1mg (AB-rated to Demulen 1/35)
Æ Ethinyl Estradiol/Norethindrone Oral Tablet, 0.035/1mg (AB-rated to Tri-Norinyl 28-Day)
Æ Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.02/0.03/0.035/1/1/1 mg (AB-rated to Estrostep FE)
Æ

Dextroamphetamine Sulfate Oral Capsule, 30 mg
- Carbidopa/Levodopa Oral Tablet, 10/100 mg
- Carbidopa/Levodopa Oral Tablet, 25/100 mg
- Carbidopa/Levodopa Oral Tablet, 25/250 mg
- Cyclosporine Oral Capsule, 25 mg
- Cyclosporine Oral Capsule, 100 mg
- Desmopressin Acetate Oral Tablet, 0.2 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 5 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 10 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 20 mg
- Dextroamphetamine Sulfate Extended Release Oral Capsule, 5 mg
- Dextroamphetamine Sulfate Extended Release Oral Capsule, 10 mg
- Dextroamphetamine Sulfate Extended Release Oral Capsule, 15 mg
- Diazepam Oral Tablet, 2 mg
- Diazepam Oral Tablet, 5 mg
- Diazepam Oral Tablet, 10 mg
- Epirubicin Injection Vial 50 mg/25 mL
- Epirubicin Injection Vial 200 mg/100 mL
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.01/0.1mg (AB-rated to Lo Seasonique)
- Ethinyl Estradiol/Norethindrone Acetate Oral Tablet, 0.02/1mg (AB-rated to Loestrin 21 1/20)
- Ethinyl Estradiol/Norethindrone Acetate Oral Tablet, 0.03/1.5mg (AB-rated to Loestrin 21 1.5/30)
- Glyburide/Metformin HC1 Oral Tablet, 1.25/250 mg
- Glyburide/Metformin HCl Oral Tablet, 2.5/500 mg
- Glyburide/Metformin HCl Oral Tablet, 5/500 mg
- Hydroxyzine Pamoate Oral Capsule, 25 mg
- Hydroxyzine Pamoate Oral Capsule, 50 mg
- Levalbuterol HCl Inhalation Solution, 0.0103%
- Levalbuterol HCl Inhalation Solution, 0.0210%
- Levalbuterol HCl Inhalation Solution, 0.042%
- Minocycline HCl Oral Capsule, 50 mg
- Minocycline HCl Oral Capsule, 75 mg
- Minocycline HCl Oral Capsule, 100 mg
- Nitrofurantoin Oral Capsules, 50 mg
- Nitrofurantoin Oral Capsules, 100 mg
- Propofol Injection Emulsion, 10 mg/mL 20 mL vial
- Propofol Injection Emulsion, 10 mg/mL 50 mL vial
- Propofol Injection Emulsion, 10 mg/mL 100 mL vial
- Propranolol HCl Oral Tablet, 10 mg
- Propranolol HCl Oral Tablet, 20 mg
- Propranolol HCl Oral Tablet, 40 mg
- Propranolol HCl Oral Tablet, 80 mg

• Current Competition Between Teva and Allergan, 5-to-4 Supplier Consolidation

- Acitretin Oral Capsule, 10 mg
- Acitretin Oral Capsule, 25 mg
- Alendronate Sodium Oral Tablet, 35 mg
- Buspirone HCl Oral Tablet, 15 mg
- Clozapine Oral Tablet, 25 mg
- Clozapine Oral Tablet, 100 mg
- Drospirenone/Ethinyl Estradiol Oral Tablet, 3/0.03 mg (AB-rated to Yasmin-28)
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.1 mg (AB-rated to Alesse-28)
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.03/0.15 mg (AB-rated to Nordette)
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.03/0.01/0.15 mg (AB-rated to Seasonique)
- Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.02/1 mg (AB-rated to Loestrin FE 1/20)
- Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.03/1.5 mg (AB-rated to Loestrin FE 1.5/30)
- Norethindrone Oral Tablet, 0.35 mg (AB-rated to Micronor 28)
- Norethindrone Oral Tablet, 0.35 mg (AB-rated to Nor-QD)

• Future Competition Between Teva and Allergan in an Existing Generic Market, 3-to-2 Supplier Consolidation

- Budesonide Inhalation Suspem8A

Æ Imiquimod Topical Cream, 3.75%
Æ Four pipeline products [2]

• Future Competition Between Teva and Allergan in a Future Generic Market, 5-to-4 Supplier Consolidation

Æ Dexmethylphenidate HCl Extended Release Oral Capsule, 25 mg
Æ Dexmethylphenidate HCl Extended Release Oral Capsule, 35 mg
Æ Fentanyl Buccal Tablet, 100 mcg
Æ Fentanyl Buccal Tablet, 200 mcg
Æ Fentanyl Buccal Tablet, 400 mcg
Æ Fentanyl Buccal Tablet, 600 mcg
Æ Fentanyl Buccal Tablet, 800 mcg
Æ Metformin HCl/Saxagliptin Extended Release Tablet, 500/5 mg
Æ Metformin HCl/Saxagliptin Extended Release Tablet, 1000/2.5 mg
Æ Metformin HCl/Saxagliptin Extended Release Tablet, 1000/5 mg

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APIs are central inputs in the manufacture of finished dose form pharmaceutical products. API supply sources must be designated in a drug's FDA marketing authorization. Switching to a non-designated API source requires a drug maker to supplement its New Drug Application or ANDA, a process that can take as long as two years or even more. Consequently, a generic drug manufacturer's API supply options are limited to the sources qualified under its ANDA. If only one API supplier is qualified under an ANDA, the ANDA holder has no immediate recourse if its designated API supplier elects to raise its prices or refuse to supply.

Teva is world's largest API supplier and supplies API to Allergan's competitors in a number of generic markets. The proposed acquisition may lessen current or future competition in fifteen pharmaceutical products markets by creating the incentive and ability for Teva to foreclose rival suppliers of fifteen newly acquired Allergan pharmaceutical products by withholding supply of the following eight Teva API products:

- Betamethasone dipropionate API;
- Betamethasone valerate API;
- Clobetasol propionate API;
- Desonide API;
- Fluocinolone API;
- Fluorouracil API;
- Probenecid API; and
- Triamcinolone acetonide API.

The fifteen downstream pharmaceutical markets in which competition would be lessened as a result of the acquisition are:

- Betamethasone dipropionate augmented ointment, 0.05%;
- Betamethasone dipropionate cream, 0.05%;
- Betamethasone dipropionate lotion, 0.05%;
- Betamethasone dipropionate ointment, 0.05%;
- Betamethasone valerate cream, 0.1%;
- Betamethasone valerate ointment, 0.1%;
- Clobetasol propionate shampoo, 0.05%;
- Clobetasol propionate ointment, 0.05%;
- Desonide cream, 0.05%;
- Probenecid tablets, 500 mg;
- Probenecid/colchicine tablets, 500 mg/0.5 mg;
- Nystatin/triamcinolone acetonide cream, 100,000 units/gm/0.1%;
- Nystatin/triamcinolone acetonide ointment, 100,000 units/gm/0.1%; and
- Two pipeline products.[3]

II. Entry

Entry into these pharmaceutical markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. Introducing generic pharmaceutical products is costly and lengthy due to drug development times and regulatory requirements, including approval by the FDA. Additionally, it can take up to two years for an API manufacturer to qualify as a new API supplier for a generic pharmaceutical product, leaving the generic pharmaceutical product with no alternative to its existing qualified API supplier or suppliers.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm by eliminating current or future competition in markets for one or more strengths of seventy-nine pharmaceutical products where the parties currently sell or are developing generic drugs. In each of these markets, Teva and Allergan are two of a limited number of current or likely future suppliers in the United States. Customers and competitors have observed that the price of generic pharmaceutical products decreases with new entry even after several suppliers have entered the market. Removal of an independent generic pharmaceutical supplier from the relevant markets in which Teva and Allergan currently compete would result in significantly higher prices post-acquisition. Similarly, the elimination of a future independent competitor would prevent the price decreases that are likely to result from the firm's entry. Thus, absent a remedy, the proposed acquisition would likely result in significantly higher prices for these generic drugs.

Additionally, the proposed acquisition likely would cause competitive harm in markets for fifteen pharmaceutical products in which Teva supplies API for a generic pharmaceutical product that currently competes or will compete in the near future with an Allergan generic pharmaceutical product. Those generic pharmaceutical markets already have or will have a limited number of competitors, some of which are supplied API by Teva. Teva has the ability to foreclose these competitors by denying them API from their only approved source. Post-acquisition, Teva would have the incentive to foreclose one or more competitors because the lost API sales would be less than the recouped profits on additional sales gained from the foreclosed competitor(s) and the increased prices. Such foreclosure would harm consumers because market concentration and price would result in significantly higher prices.

IV. The Consent Agreement

The remedy reflected in the proposed Consent Agreement would eliminate the likely anticompetitive effects of the proposed acquisition by requiring the parties to divest rights and assets related to the pharmaceutical products in each relevant market. The acquirers are: Mayne Pharma Group Ltd. (''Mayne''), Impax Laboratories, Inc. (''Impax''), Dr. Reddy's Laboratories Ltd. (''Dr. Reddy's''), Sagent Pharmaceuticals, Inc. (''Sagent''), Cipla Limited (''Cipla''), Zydus Worldwide DMCC (''Zydus''), Mikah Pharma LLC (''Mikah''), Perrigo Pharma International D.A.C. (''Perrigo''), Aurobindo Pharma USA, Inc. (''Aurobindo''), Prasco LLC (''Prasco''), and 3M Company (''3M'') (collectively, the ''Acquirers''). The parties must

[2] Teva's and Allergan's independent development projects for two overlapping pharmaceutical products are not public, and their existence is confidential business information. But for the proposed acquisition, certain strengths of the Teva and Allergan products would likely compete in four future markets. To preserve the confidentiality of these development programs, the specific future markets in which these products would compete are not identified in this document, and references to these products have been redacted from the public version of the Complaint.

[3] Allergan has not yet made public the development of two pharmaceutical products that would likely compete with products for which Teva supplies API. To preserve the confidentiality of these Allergan development programs, the specific markets in which these likely future products would compete are not identified in this document, and references to these products have been redacted from the public version of the Complaint.

divest the products no later than ten days after the acquisition.

The Commission's goal in evaluating possible acquirers of divested assets is to maintain the competitive environment that existed prior to the acquisition. The Commission thoroughly reviewed the assets to be divested, the transitional services to be provided by Teva, and the capabilities and plans of each Acquirer. The interim monitors, who will oversee the

[1] This market share data is based on 2014 IMS gross sales data.

[2] In addition to selling finished pharmaceutical products, Teva and Allergan also sell active pharmaceutical ingredients (API) to many third-party drug manufacturers, including parties that will now compete with the merged entity. Where the number of competitors in the finished product market is limited, the Commission determined that this vertical relationship could raise competitive

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undermine competition in the pharmaceutical industry.

By direction of the Commission.

Donald S. Clark,

[FR Doc. 2016–18562 Filed 8–4–16; 8:45 am]

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FEDERAL TRADE COMMISSION

[File No. 1623034, Docket No. C–4580]

Very Incognito Technologies, Inc., Doing Business as Vipvape

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: The Commission has approved a final consent order in this matter, settling alleged violations of federal law prohibiting deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the Complaint and the terms of the Decision and Order.

DATES: Issued on June 21, 2016.

SUPPLEMENTARY INFORMATION:

Analysis of Agreement Containing Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has approved a final consent order applicable to Very Incognito Technologies, Inc. dba Vipvape (''Vipvape'').

The consent order was placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period became part of the public record. After the public comment period, the Commission reviewed the agreement and the comments received, and determined to make the proposed order final.

This matter concerns allegedly false representations that Vipvape made to consumers concerning its participation in the Asia-Pacific Economic Cooperation (''APEC'') Cross Border Privacy Rules (''CBPR'') system. The APEC CBPR system is a voluntary, enforceable mechanism that certifies a company's compliance with the principles in the CBPR and facilitates privacy-respecting transfers of data amongst APEC member economies. The APEC CBPR system is based on nine data privacy principles: Preventing harm, notice, collection limitation, use choice, integrity, security safeguards, access and correction, and accountability. Companies that seek to participate in the APEC CBPR system must undergo a review by an APEC-recognized Accountability Agent, which certifies companies that meet the standards.

Companies under the FTC's jurisdiction are eligible to apply for APEC CBPR certification. The names of certified companies are posted on a public-facing Web site, . . . Companies must re-apply annually in order to retain their status as current participants in the APEC CBPR system. A company that falsely claims APEC CBPR participation may be subject to an enforcement action based on the FTC's deception authority under Section 5 of the FTC Act.

Vipvape makes and distributes hand-held vaporizers. According to the Commission's complaint, Vipvape has set forth on its Web site, ://. / /. / / , privacy policies and statements about its practices, including statements related to its participation in the APEC CBPR system.

The Commission's complaint alleges that Vipvape falsely represented that it was a participant in the APEC CBPR system when, in fact, it never sought or obtained certification.

Part I of the order prohibits Vipvape from making misrepresentations about its participation in any privacy or security program sponsored by a government or any self-regulatory or standard-setting organization, including, but not limited to, the APEC CBPR system.

Parts II through VI of the order are reporting and compliance provisions. Part II requires acknowledgment of the order and dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part III ensures notification to the FTC of changes in corporate status and mandates that Vipvape submit an initial compliance report to the FTC. Part IV requires Vipvape to retain documents relating to its compliance with the order for a five-year period. Part V mandates that Vipvape make available to the FTC information or subsequent compliance reports, as requested. Part VI is a provision that ''sunsets'' the order on June 21, 2036, with certain exceptions.

The purpose of this analysis, which was placed on the Commission Web site on May 4, 2016, was to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or order or to modify the order's terms in any way.

By direction of the Commission.

Donald S. Clark,

[FR Doc. 2016–18566 Filed 8–4–16; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 161–0102]

Mylan N.V.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before August 29, 2016.

ADDRESSES: Interested parties may file a comment at ://. / / online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''In the Matter of Mylan N.V., File No. 161–0102—Consent Agreement'' on your comment and file your comment online at ://. / / by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''In the Matter of Mylan N.V., File No. 161–0102—Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Christina Perez (202–326–2350), Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final