**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

CVS PHARMACY, INC.,
RITE AID CORPORATION and
RITE AID HDQTRS. CORP.,

Plaintiffs,

vs.

ABBVIE INC.; ALLERGAN, INC.; ALLERGAN SALES, LLC; ALLERGAN USA, INC.; FOREST LABORATORIES, INC.; FOREST LABORATORIES HOLDINGS, LTD.; FOREST LABORATORIES IRELAND, LTD.; FOREST LABORATORIES, LLC; HETERO USA INC.; HETERO LABS LTD.; HETERO DRUGS LTD.; TORRENT PHARMACEUTICALS LTD.; TORRENT PHARMA INC.; ALKEM LABORATORIES LTD.; ASCEND LABORATORIES, LLC; INDCHEMIE HEALTH SPECIALTIES PRIVATE LTD.; GLENMARK GENERICS INC., USA; GLENMARK GENERICS LTD.; GLENMARK PHARMACEUTICALS LTD.; AMERIGEN PHARMACEUTICALS, INC.; AMERIGEN PHARMACEUTICALS, LTD.; WATSON LABORATORIES, INC. (NV); WATSON LABORATORIES, INC. (DE); WATSON LABORATORIES, INC. (NY); WATSON LABORATORIES, INC. (CT); WATSON PHARMA, INC.; WATSON PHARMACEUTICALS, INC.; ACTAVIS, INC.; TEVA PHARMACEUTICAL INDUSTRIES LTD.; and TEVA PHARMACEUTICALS USA, INC.,

Defendants.

CASE NO. 1:20-cv-10087

JURY TRIAL DEMANDED

**COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs CVS Pharmacy, Inc., Rite Aid Corporation and Rite Aid Hdqtrs. Corp. ("Plaintiffs") sue Defendants AbbVie Inc. ("AbbVie"); Allergan, Inc., Allergan Sales, LLC, and Allergan USA, Inc. (collectively, "Allergan"); Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Forest Laboratories, LLC, and Forest Laboratories Ireland Ltd. (collectively, "Forest"); Hetero USA Inc., Hetero Labs Ltd. and Hetero Drugs Ltd. (collectively "Hetero"); Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively "Torrent"); Alkem Laboratories Ltd. and Ascend Laboratories, LLC ("Alkem"); Indchemie Health Specialties Private Ltd. ("Indchemie"); Glenmark Generics Inc., USA, Glenmark Generics Ltd. and Glenmark Pharmaceuticals Ltd. (collectively "Glenmark"); Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. (collectively "Amerigen"); and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Actavis, Inc., Watson Pharma, Inc., Watson Pharmaceuticals, Inc., Teva Pharmaceuticals Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Watson"), for Defendants' violations of the antitrust laws relating to the pharmaceutical drug Bystolic (nebivolol hydrochloride) ("Bystolic"). For their Complaint, Plaintiffs allege as follows:

## I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages and other relief arising out of the Defendants' unlawful exclusion of generic substitutes for the branded drug Bystolic, otherwise known as nebivolol hydrochloride or nebivolol HCl, a "beta blocker" used to treat high blood pressure. Forest and its successors, Allergan and AbbVie (collectively the "Brand Defendants"), manufacture and sell Bystolic which generates annual sales of more than $500 million in the United States. Although would-be generic manufacturers began filing Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration (the

"FDA") to market generic nebivolol HCl on December 17, 2011,[1] no generic competitor has entered or will enter until September 17, 2021.

2. The only material difference between generic and brand name drugs is their price. Generics are at least 20% cheaper than their branded counterparts when only one generic is on the market and at least 50% cheaper when there are multiple generic competitors on the market. As a result, generics constitute both (a) an opportunity for drug purchasers to obtain enormous cost savings and (b) a serious threat to the monopoly power and profits of the manufacturer of the corresponding brand name drug. Due to their lower price, AB-rated generics typically take 80% or more of the sales of a drug molecule from the brand name product within six months of generic entry. These extremely rapid erosion rates of the brand manufacturer's sales are encouraged by state drug substitution laws, which permit (and in some cases require) dispensing pharmacies like the ones owned and operated by Plaintiffs to substitute available AB-rated generic drugs for a brand drug unless the prescribing physician specifically orders otherwise (by indicating that the drug should be "dispensed as written" or its equivalent).

3. Acutely aware of these realities, Forest (and its successors) engineered a series of unlawful reverse-payment deals (also known as "pay for delay" deals) with each of its would-be generic competitors, specifically, Hetero, Torrent, Alkem, Indchemie, Glenmark, Amerigen and Watson (collectively, the "Generic Defendants"). From October 2012 through November 2013, Forest entered into these serial deals pursuant to which each generic (1) agreed not to compete with Forest or enter the market prior to September 17, 2021, unless another generic competitor entered the market earlier; and in exchange (2) received "side-deals," and cash payments, the

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[1] *See, e.g.*, 11/27/2015 Letter from Food and Drug Administration ("FDA") to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf.

precise amounts of which have not been publicly disclosed except that they each exceed $15,000,000 in value. As corporate successors to Forest, Allergan and then AbbVie have continued this illegal collusion and unreasonable restraint of trade in the market for nebivolol HCl, all at the expense of purchasers. Every month of delayed generic competition has allowed Forest and its successors to unlawfully maintain many millions of dollars in monopoly profits from Bystolic that it would have otherwise lost to the Generic Defendants in the absence of Forest's large and unjustified payments to the Generic Defendants to delay generic Bystolic.

4. Beginning on December 17, 2011,[2] after the Generic Defendants became the first generic manufacturers to seek approval from the FDA to market generic Bystolic, Forest sued each of them, accusing them of allegedly infringing U.S. Patent No. 6,545,040 (the "'040 Patent"), which Forest submitted for listing in the FDA Orange Book by certifying that the patent covered Bystolic. These suits, filed in mid-March 2012, automatically triggered stays of FDA approval of the generic products (meaning that regardless of the merits of the patent infringement actions, the FDA could not finally approve any of the Generic Defendants to launch generic Bystolic before June 18, 2015 absent an earlier favorable decision for the Generic Defendants or a dismissal of the actions). Foreclosing the Generic Defendants from launching also foreclosed all other generic manufacturers of Bystolic. As the first manufacturers to file for approval of generic Bystolic, the Generic Defendants were eligible to share 180 days of market exclusivity during which no other generic Bystolic product could be sold (other than a generic marketed

[2] *See, e.g.*, 11/27/2015 Letter from FDA to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf; 5/27/2017 Letter from FDA to Glenmark, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf; 6/24/2015 Letter from FDA to Alkem, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203741Orig1s000ltr.pdf.

under Forest's approved NDA, known as an "authorized generic").

5. Between March 2012 and November 2013, while the stays were in effect, the Generic Defendants defended the patent infringement suits and prepared to bring their generic Bystolic products to market to compete with Forest's branded Bystolic. At least six of the seven Generic Defendants would have been ready to launch well before September 17, 2021, as each had final FDA approval to do so as set forth in the table below:

| Manufacturer | ANDA No. | Final Approval Date |
|---|---|---|
| Amerigen | 203659 | 4/16/15 |
| Watson | 203683 | 11/27/15 |
| Alkem | 203741 | 6/24/15 |
| Glenmark | 203821 | 5/25/17 |
| Indchemie | 203828 | 7/29/15 |
| Torrent | 203966 | 3/2/18 |

6. The Generic Defendants would have succeeded in the patent litigation because the '040 Patent was weak. The '040 Patent litigation likely would have concluded by mid-2015, including all appeals. The Generic Defendants would have won and launched by the later of: (a) June 2015, which was the expiry of the only other patent that Forest contended covered Bystolic, U.S. Patent No. 5,759,580 (the "'580 Patent"), or (b) the date their ANDAs were finally approved. Rather than risk facing competition from the Generic Defendants as early as June 2015 and the subsequent reduction in Bystolic brand sales and revenues such competition would cause, Forest paid each of the Generic Defendants to stay off of the market until September 21, 2021.

7. The side-deals that Forest provided to each Generic Defendant were intended to shield Forest from the risk of competition, and the Generic Defendants readily accepted these exclusionary side-deals to quit the patent fight.

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