OFFICE OF THE ATTORNEY GENERAL
OF THE STATE OF NEW YORK

Assurance No. 14-034

In the Matter of the

Investigation by Eric T. Schneiderman, Attorney General of the State of New York, Concerning an Agreement Between Competing Pharmaceutical Companies to Not Challenge Each Other's Sole First to File Exclusivity

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ASSURANCE OF DISCONTINUANCE
PURSUANT TO NEW YORK'S DONNELLY ACT
AND NEW YORK EXECUTIVE LAW § 63(15)

In 2010, Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy") and Teva Pharmaceuticals USA, Inc. ("Teva"), two generic pharmaceutical manufacturers (the "Parties"), entered into an agreement relating to atorvastatin calcium, the generic version of Lipitor®, a drug used to treat high cholesterol. The agreement focused on the Parties' future sale of generic atorvastatin product in the United States, but it also contained an unusual provision. That provision provided that for the duration of the agreement and two years thereafter, the Parties would refrain from challenging each other's regulatory exclusivity rights for all of their drugs that, as of the date of the agreement, were subject to applications filed with the Food and Drug Administration ("FDA"). In late 2012, the Office of the Attorney General of the State of New York ("OAG") commenced a confidential investigation into whether this broad "no-challenge" provision constituted an unlawful anticompetitive agreement under federal and state antitrust laws (the "Investigation"). In the course of its Investigation, OAG reviewed documents from the Parties and took testimony from the Parties.

This Assurance of Discontinuance ("Assurance") contains the findings of OAG's Investigation and the relief agreed to by OAG and the Parties.

ATTORNEY GENERAL'S FINDINGS

A. Relevant Parties

1. Ranbaxy and its affiliates have offices and facilities in various locations in the United States, including Jacksonville, Florida. Ranbaxy's primary business in the United States is the sale of generic pharmaceutical drugs. In 2012, its revenues from the sale of pharmaceuticals in North America exceeded $1 billion.

2. Teva is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Teva is the U.S. subsidiary of Teva Pharmaceutical Industries Limited, the world's largest manufacturer of generic pharmaceuticals. Teva's primary business in the United States is the sale of generic pharmaceuticals. In 2012, Teva's sales of generics in the United States exceeded $4 billion.

B. Regulation of Pharmaceuticals in the United States

3. The sale of pharmaceuticals in the United States is heavily regulated. Before a company may lawfully sell a drug in the United States, it must first obtain regulatory approval from the FDA. A company seeking FDA approval to market a new drug (*i.e.*, a branded drug) must file a New Drug Application ("NDA") demonstrating the safety and efficacy of its product. In contrast, because Congress sought to encourage and facilitate generic competition, a company seeking FDA approval to market a generic version of an approved branded drug may take

advantage of the safety and efficacy evidence in the NDA, and need only submit an "abbreviated" new drug application ("ANDA") that confirms that the generic is "bioequivalent" to the branded drug.[1]

4. When a brand name drug is covered by one or more patents, a generic drug company that seeks to market a generic version of the drug prior to expiration of any patents may proceed to seek FDA approval, but generally must certify in the ANDA that either: (1) its generic product does not infringe the patents on the brand-name drug, or (2) that the patents are invalid and/or unenforceable.

5. As an incentive to encourage generic manufacturers to challenge the patent(s) claimed to cover brand drugs, or to design around those patents, in order to make lower-priced generic drugs available to patients more quickly, the first company to file an ANDA that challenges a branded drug company's patents may be eligible for 180 days of market exclusivity for its generic product during which no other ANDAs for the same product that included a challenge to the brand company's patents may be approved. This exclusivity period is often referred to as "180-day exclusivity" or "first to file exclusivity."

6. Frequently, first to file exclusivity is held by only one generic manufacturer ("Sole First to File Exclusivity" or "SFFE"), in which case the first-filer generally can sell its product free from competition by other generic applicants during the 180-day period. Also frequently, first to file exclusivity may be held jointly by multiple generic manufacturers, in

[1] A generic is "bioequivalent" to a branded drug when the rate and extent of absorption of the generic drug is not significantly different from the rate and extent of absorption of the branded drug, when administered at the same dosage. *See* 21 CFR 320.1. ANDAs must satisfy certain other requirements aside from bioequivalence that are not relevant here.

which case all of the joint holders may enter during the 180-day period – but no others. Notwithstanding the foregoing, if it so chooses, the brand manufacturer is permitted to sell its own "authorized generic" version of the product during the 180-day exclusivity period, whether the first to file exclusivity is held by one applicant or several.

7. Under certain circumstances, a company may lose or forfeit first to file exclusivity on particular drug(s). As explained in more detail below, one way in which generic companies may compete with each other is to challenge each other's Sole First to File Exclusivities. If such a challenge is successful, it may move up the date upon which the challenger and other competitors can enter the market, and thus benefit consumers by means of more quickly lowering generic prices. The OAG believes that a generic manufacturer's challenge to a competing generic manufacturer's SFFE can be analogized to a challenge by a generic manufacturer to a brand name manufacturer's patent, which may similarly result in earlier and greater generic competition.

C. Consumer Benefits of Generic Pharmaceuticals

8. Although therapeutically the same as their branded counterparts, generics are typically priced significantly lower. For this reason, the availability of generic drugs saves consumers and other purchasers billions of dollars annually.

9. The first generic drug to enter the market typically sells at a significant discount to the price at which the brand product was sold prior to generic entry. But the savings from the

availability of generic drugs accelerates significantly as more companies selling the same generic drug enter the market, which typically causes the average generic price to fall even further.[2]

D. The Importance of SFFEs and Challenges to SFFEs

10. Generic pharmaceutical companies, including Teva and Ranbaxy, compete in many ways, including price, quality, and product offerings. One means by which generics compete is by seeking Sole First to File Exclusivity. Generic drug manufacturers seek SFFE because typically, both prices and sales volumes are higher during exclusivity than afterwards. Moreover, even after exclusivity expires and other generics enter the market, the generic that had the SFFE is often able to retain a greater market share than competing generics. Obtaining and protecting first to file exclusivity, and especially SFFE, is an important part of both Teva's and Ranbaxy's business strategy.

11. When a generic company is not awarded first to file exclusivity for a particular product because it is awarded to a different generic manufacturer instead, it may compete by challenging the FDA's grant of exclusivity to its competitor. As noted, challenging SFFE may be beneficial to the challenger because a successful challenge is likely to lead to quicker market entry and higher sales volumes for the challenger (as well as other sellers of the same generic product) because the relevant federal statute no longer prohibits entry by other generic manufacturers during the 180-day period.

[2] *See, e.g.*, Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impacts* (2011). In addition, the copay amount that an insurer requires an enrollee to pay upon filling a prescription typically is lower for generic drugs than for their brand counterparts.

12. Successful challenges to SFFEs can have significant benefits for consumers and/or other health care payors. Because competition among generics typically means lower generic prices, loss or forfeiture of SFFE is likely to result in a significantly faster decrease in generic drug prices. As indicated above, the effect of a successful challenge to an SFFE is not unlike the effect of a successful challenge to a brand manufacturer's patent – faster and greater entry of multiple generic competitors, leading to faster and greater price reductions.

13. Challenges to SFFEs may be made either by written submission to the FDA, for example through the filing of a "Citizen Petition," or by filing litigation and asking a court to compel the FDA to declare that exclusivity has been lost or forfeited, or that it was mistakenly awarded in the first place.

E. Ranbaxy and Teva's Atorvastatin Collaboration

14. In August 2002, Ranbaxy was the first generic drug manufacturer to file an ANDA seeking to market generic atorvastatin calcium (a statin), the branded version which is sold by Pfizer under the brand name Lipitor®. Although Teva and other generics also filed ANDAs for generic atorvastatin calcium, it was generally believed in the industry that Ranbaxy was eligible to receive Sole First to File Exclusivity, and thus, a 180 day period during which it could sell its generic atorvastatin free from competition by other generic versions of the drug (except the authorized generic version that Pfizer had licensed to Watson).

15. Pfizer filed patent litigation against both Ranbaxy and Teva, as well as other ANDA filers, alleging infringement of patents it claimed for Lipitor®. Both litigations settled. As part of its settlement with Pfizer, Ranbaxy received a license from Pfizer allowing it to sell its

generic atorvastatin as of November 30, 2011, and agreed that it would not begin selling Ranbaxy's generic atorvastatin product prior to that date.

16. In February 2009, FDA invoked its Application Integrity Policy ("AIP") against certain Ranbaxy facilities, including Paonta Sahib, the facility from which Ranbaxy intended to manufacture its generic atorvastatin. As a result of the AIP, FDA suspended substantive scientific review of all ANDAs "that contain data developed at the Paonta Sahib site," which included Ranbaxy's atorvastatin ANDA.

17. Because the AIP suspended review of its generic atorvastatin ANDA, Ranbaxy had substantial concerns as to whether it would obtain final FDA approval for atorvastatin by November 30, 2011. Thus, in or about March 2010 Ranbaxy began negotiations with Teva on an agreement that, if certain events occurred, would have permitted Teva to launch its own generic atorvastatin product on or before November 30, 2011 (and with the potential to bring generic atorvastatin to market as much as five months earlier than Ranbaxy's license date, depending on the timing of FDA approval for Teva's ANDA). This would enable Ranbaxy to obtain some financial benefit if Ranbaxy's ANDA was not timely approved

18. On December 7, 2010, Teva and Ranbaxy executed the agreement ("2010 Agreement").

19. Although the 2010 Agreement concerned the sale of only atorvastatin, it also contained a provision (described in more detail below) that applies much more broadly. This provision provided that neither company would challenge *any* of each other's ANDAs filed with FDA as of the effective date of the agreement for *any* reason whatsoever for a period of at least two years. This commitment included, among other things, an agreement not to challenge each

other's SFFEs (the "No Challenge Provision") for ANDAs that were filed as of the effective date of the agreement.

20. On November 30, 2011, Ranbaxy did in fact obtain FDA approval for generic atorvastatin and launched commercial sales of the drug the next day.

21. Ranbaxy's Sole First to File Exclusivity for atorvastatin ended on May 29, 2012. However, the No Challenge Provision remains in effect until May 29, 2014.

F. The Parties' Mutual Commitment Not to Challenge Each Others' SFFEs

22. In the broader provision containing the No Challenge Provision, the Parties agreed that for the duration of the agreement and a period of two years thereafter, neither would challenge the viability of, or regulatory exclusivities for, each other's then pending ANDAs for any reason. As written in the 2010 Agreement, the full provision provides:

> 6.10.6. In recognition of the Parties' exchange of Confidential Information necessary for the implementation and operation of this Agreement, *during the Term of this Agreement, and for a period of two (2) years thereafter, a Party shall not, directly or indirectly, challenge the other Party's right to First to File Exclusivity for any ANDA filed as of the Effective Date, or the viability, completeness or status of any ANDAs, filed with FDA as of the Effective Date.* Teva covenants, to the extent that it has previously challenged Ranbaxy's eligibility for First to File Exclusivity related to the Ranbaxy ANDA and/or the Ranbaxy Product, that Teva will provide Ranbaxy with copies of any such documents and/or correspondence regarding such challenges and Teva shall immediately cease any of such challenges and shall also formally withdraw any of such challenges, including, without limitation, making communications to the FDA, in the form and upon the approval of Ranbaxy, in support of Ranbaxy's eligibility for First to File Exclusivity. Notwithstanding the foregoing, this Section 6.10.6 shall not apply to Ranbaxy solely with respect to Product in the event that and to the extent that Ranbaxy challenges an FDA final determination that Ranbaxy should not be awarded First to File

> Exclusivity for the Ranbaxy Product as specified in Section 2.8.2(i). (emphasis added)

23. The OAG considers the No Challenge Provision – *i.e.*, the commitment by both Parties not to challenge each other's SFFEs filed with FDA as of the effective date of the agreement – to be an unreasonable agreement between direct competitors not to compete, unlawful under the antitrust laws. The Parties agreed that for any drug for which each party had an ANDA and one party has a claim to SFFE, the other party would refrain from challenging the other's right to the SFFE for that product. The No Challenge Provision can be analogized to a commitment by a generic company not to challenge a brand manufacturer's patents; and in this case it had the effect of prohibiting the Parties from challenging each other's SFFEs for *dozens* of drugs – which the OAG views as unrelated to the collaboration – and for *any* reason whatsoever. The OAG views this provision as analogous to an agreement between competitors to divide markets, which could be *per se* illegal, but even if not *per se* illegal, the OAG believes that the commitments by the Parties not to challenge each other's SFFEs are inherently suspect under the antitrust laws and would be presumed unlawful by a court.

24. The OAG investigated whether the No Challenge Provision was reasonably necessary to allow Ranbaxy and Teva to share confidential information with one another in furtherance of the atorvastatin collaboration, but concluded that it was not. The OAG concluded:

a. The information that needed to be shared between the Parties to permit the atorvastatin collaboration to succeed was very limited. Moreover, other provisions of the 2010 Agreement were adequate to prevent abuse of confidential

information shared, for example, another provision of that agreement forbade the Parties from disclosing or using confidential information except in furtherance of the transactions contemplated by the collaboration.

b. The No Challenge Provision was also not narrowly tailored to address any legitimate confidentiality concerns, as required by the applicable law. As part of a collaboration for marketing one drug, the No Challenge Provision prevents the Parties from challenging each other's SFFEs for dozens of drugs and for any reason – regardless of the factual or legal basis for the challenge, and whether or not the challenge is based upon information obtained from the collaboration.

c. There were numerous alternatives available to the Parties for addressing any legitimate confidentiality concerns that would have been less restrictive than the broad No Challenge Provision. For example, the Parties could have reduced the scope of information shared under the agreement, and/or agreed to strict firewalls limiting who at each company received access to information shared during the collaboration.

25. OAG believes that the No Challenge Provision is either *per se* unlawful or presumptively unlawful, and thus illegal regardless of whether any real-world anticompetitive effects can be identified that were caused by it. The OAG did not identify any such effects.

AGREEMENT AND PROSPECTIVE RELIEF

WHEREAS, each of Ranbaxy and Teva neither admits nor denies the OAG's Findings (1)–(25) above;

WHEREAS, OAG is willing to accept the terms of this Assurance of Discontinuance ("Assurance" or "AOD") pursuant to New York Executive Law § 63(15) and New York General Business Law § 343, and discontinue its Investigation of the Parties;

WHEREAS, each of the Parties believes that the obligations imposed by this Assurance are prudent and appropriate;

IT IS HEREBY UNDERSTOOD AND AGREED by and between the Parties and the OAG that:

1. This Assurance shall apply to each of the Parties and any and all of their successors, whether acting through their principals, directors, officers, shareholders, employees, representatives, agents, assigns, successors, parents, subsidiaries, affiliates, or other business entities, whose acts, practices, or policies are directed by either of the Parties or any successor thereof. By signing, each of the Parties stipulates that it foregoes any legal defenses to, or assertions against, the enforceability of this Assurance.

2. In consideration of the making and execution of this Assurance, and within twenty (20) business days thereafter, each of the Parties agrees to make a monetary payment by wire transfer, certified or bank check payable to the State of New York in the amount of $150,000.

3. Any payments related to this Assurance must reference Assurance # 14-034.

4. Each of the Parties agrees that it will not enforce or abide by the No Challenge Provision, and deems it to be null and void. Each of the Parties specifically agrees that it is no longer obligated to refrain from challenging, under the No Challenge Provision, Sole First to File Exclusivities held by the other. Each of the Parties disclaims any right to prevent one another, under the No Challenge Provision, from challenging each other's Sole First to File Exclusivities.

5. Each of the Parties agrees that it will not enter into any agreement(s) with another generic company containing a provision not to challenge or otherwise take any adverse action against another generic company's Sole First to File Exclusivity for a drug that is intended or likely to be sold in New York State, unless reasonably ancillary to a procompetitive agreement.

6. OAG has agreed to the terms of this Assurance based on, among other things, the representations made to OAG by each of the Parties and its respective counsel, and OAG's own factual investigation as set forth in Findings (1)-(25) above. To the extent that any material representations by a Party are later found to be inaccurate or misleading, this Assurance is voidable as to that Party by the OAG in its sole discretion.

7. No representation, inducement, promise, understanding, condition, or warranty not set forth in this Assurance has been made to or relied upon by either of the Parties in agreeing to this Assurance.

8. Each Party represents and warrants, through the signatures below, that the terms and conditions of this Assurance are duly approved, and execution of this Assurance is duly authorized. Each Party and its undersigned counsel represents and warrants that its undersigned counsel is authorized to execute this Assurance on behalf of such Party. Neither Party shall take

any action or make any statement denying, directly or indirectly, the propriety of this Assurance or expressing the view that this Assurance is without factual basis. Nothing in this paragraph affects either Party's (i) testimonial obligations or (ii) right to take legal or factual positions in defense of litigation or other legal proceedings to which OAG is not a party. This Assurance is not intended for use by any third party in any other proceeding and is not intended, and should not be construed, as an admission of liability by the Parties or either of them.

9. This Assurance may not be amended except by an instrument in writing signed on behalf of all of the parties to this Assurance.

10. This Assurance shall be binding on and inure to the benefit of the parties to this Assurance and their respective successors and assigns, provided that each of Teva and Ranbaxy may not assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without the prior written consent of OAG.

11. In the event that any one or more of the provisions contained in this Assurance shall for any reason be held to be invalid, illegal, or unenforceable in any respect, in the sole discretion of the OAG, such invalidity, illegality, or unenforceability shall not affect any other provision of this Assurance.

12. To the extent not already provided under this Assurance, the Parties shall, upon request by OAG, provide all documentation and information necessary for OAG to verify compliance with this Assurance.

13. All notices, reports, requests, and other communications to any party pursuant to this Assurance shall be in writing and all notices directed to the OAG should be sent to the

Antitrust Bureau Chief at 120 Broadway, 26th Floor, New York, NY 10271-0332.

14. Acceptance of this Assurance by OAG shall not be deemed approval by OAG of any of the practices or procedures referenced herein, and the Parties shall make no representation to the contrary.

15. Pursuant to Exec. Law § 63(15), evidence of a violation of this Assurance by a Party shall constitute *prima facie* proof of violation of the applicable law by that Party in any action or proceeding thereafter commenced by OAG.

16. If a court of competent jurisdiction determines that a Party has breached this Assurance, that Party shall pay to OAG the cost, if any, of such determination and of enforcing this Assurance, including, without limitation legal fees, expenses, and court costs.

17. Either Party shall be entitled to petition the OAG to alter, modify, or set aside, in whole or in part, this AOD on the grounds that conditions of fact or law have so changed as to require such action or the public interest requires it.

18. The OAG finds the relief and agreements contained in this Assurance appropriate and in the public interest. The OAG is willing to accept this Assurance pursuant to Exec. Law § 63(15), in lieu of commencing a statutory proceeding. This Assurance shall be governed by the laws of the State of New York without regard to any conflict of laws principles.

19. Nothing contained herein shall be construed as to deprive any person of any private right under the law.

20. This Assurance of Discontinuance will terminate, without any further action by the Parties, five (5) years from the last date signed by the Parties.

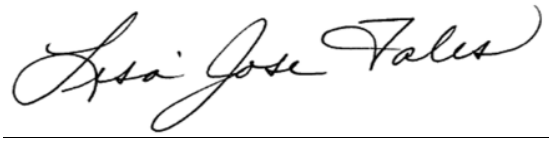
IN WITNESS WHEREOF, this Assurance is executed by the parties this 11th day of February, 2014

ERIC T. SCHNEIDERMAN

Attorney General of the State of New York
The Capitol
Albany, NY 12224-0341

By: _____
Eric J. Stock, Esq.
Chief, Antitrust Bureau

Ranbaxy Pharmaceuticals, Inc.

By: 
Lisa Jose Fales, Esq.
Counsel for Ranbaxy Pharmaceuticals, Inc.

Teva Pharmaceuticals USA, Inc.

By: _____
Christopher T. Holding, Esq.
Counsel for Teva Pharmaceuticals USA, Inc.

IN WITNESS WHEREOF, this Assurance is executed by the parties this 12th day of February, 2014

ERIC T. SCHNEIDERMAN

Attorney General of the State of New York
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Albany, NY 12224-0341

By: _____
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Ranbaxy Pharmaceuticals, Inc.

By: _____
Lisa Jose Fales, Esq.
Counsel for Ranbaxy Pharmaceuticals, Inc.

Teva Pharmaceuticals USA, Inc.

By: _____
Christopher T. Holding, Esq.
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IN WITNESS WHEREOF, this Assurance is executed by the parties this 18th day of February, 2014

ERIC T. SCHNEIDERMAN

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