EXHIBIT A

SUPREME COURT OF THE STATE OF NEW YORK
NEW YORK COUNTY

TEAMSTERS LOCAL 404 HEALTH SERVICES & INSURANCE PLAN

Petitioner,

-against-

KING PHARMACEUTICALS, INC., MERIDIAN MEDICAL TECHNOLOGIES, INC., and PFIZER INC.,

Respondents.

Index No.

PETITION OF TEAMSTERS LOCAL 404 HEALTH SERVICES AND INSURANCE PLAN FOR PRE-COMPLAINT DISCOVERY PURSUANT TO CPLR § 3102(c)

Petitioner Teamsters Local 404 Health Services and Insurance Plan ("Teamsters Local 404") respectfully requests that this Court grant Teamsters Local 404 leave to obtain pre-complaint discovery pursuant to CPLR § 3102(c) to better frame, and particularize its antitrust action against Respondents King Pharmaceuticals, Inc., Meridian Medical Technologies, Inc., and Pfizer, Inc. Petitioner attaches the *Declaration of Patrick J. Coughlin in Support of an Order to Show Cause for Pre-Complaint Discovery Pursuant to CPLR § 3102(c)*, dated April 29, 2015, as Exhibit A hereto.

Dated: April 30, 2015

Respectfully submitted,

By: *Michael M. Buchman*

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SUPREME COURT OF THE STATE OF NEW YORK
NEW YORK COUNTY

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TEAMSTERS LOCAL 404 HEALTH SERVICES & INSURANCE PLAN

Petitioner,

-against-

KING PHARMACEUTICALS, INC., MERIDIAN MEDICAL TECHNOLOGIES, INC., and PFIZER INC.,

Respondents.

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Index No.

DECLARATION OF PATRICK J. COUGHLIN IN SUPPORT OF AN ORDER TO SHOW CAUSE FOR PRE-COMPLAINT DISCOVERY OF KING PHARMACEUTICALS, INC., MERIDIAN MEDICAL TECHNOLGIES, INC., AND PFIZER INC. PURSUANT TO CPLR § 3102(c)

I, PATRICK J. COUGHLIN, an attorney admitted to practice in the courts of this State, affirm the following under penalties of perjury pursuant to CPLR § 2106:

1. I am Of Counsel at Robbins Geller Rudman & Dowd LLP and submit this Declaration in support of the Teamsters Local 404 Health Services and Insurance Plan's ("Teamsters Local 404") petition seeking extremely narrow pre-complaint discovery, pursuant to New York Civil Practice Law and Rules § 3102(c), from Respondents.

A. The Nature of the Request

2. The Petitioner seeks the production of the settlement agreement(s), licensing agreement(s), and any other related agreement(s) (collectively the "Agreements") that Pfizer Inc. and/or its subsidiaries, Meridian Medical Technologies, Inc. ("Meridian") and King Pharmaceuticals, Inc. ("King") (Pfizer Inc. and its subsidiaries collectively "Pfizer") and Mylan Inc. ("Mylan"), entered into with: (i) Teva Parenteral Medicines, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Teva"), on or about April 27, 2012 ("Teva Agreement").

3. The Teva Agreement was reached in resolution of *King Pharmaceuticals, Inc., et al, v. Teva Parenteral Medicines, Inc., et al.*, United States District Court, District of Delaware, No. 1:09-cv-00652, concerning an epinephrine auto-injector generic product ("Teva Litigation").

4. An epinephrine auto-injector is a single-use delivery system for epinephrine. Epinephrine is used to treat signs and symptoms of anaphylactic shock triggered by life-threatening allergic reactions. The auto-injector is intended to be self-administered in an emergency by the patient suffering the attack of anaphylactic shock, or administered by a parent, teacher, or by-stander to the attack.

5. Pfizer, Mylan, Meridian, and King (collectively, "Brand Defendants") manufacture, distribute, market, sell, or license a brand name auto-injector known as the EpiPen Auto-Injector and the EpiPen Jr. Auto-Injector, which they tout as the "Most Prescribed Self Injectable Epinephrine."

6. EpiPen is the brand-name epinephrine auto-injector originally approved for use by the Food and Drug Administration ("FDA") in 1987. In 2012, Thomas Handel, a Meridian Senior Vice President of Sales and Marketing, testified that the EpiPen brand holds 99% of the market of self-injectable epinephrine.

7. Teva has developed and is close to launching a generic version of the EpiPen, which poses a threat to Respondents' monopoly. In order to prevent or delay generic entry, Respondents filed the Teva Litigation.

8. Delaying the entry of a generic or alternative self-injectable epinephrine would allow Pfizer and its subsidiaries to retain millions of dollars in unlawful monopoly profits.

9. Upon information and belief, in the guise of settling patent litigation, the Brand Defendants and Teva unlawfully entered into an agreement whereby the Brand Defendants

provided significant consideration, incentives, and benefits to Teva to delay bringing their competing products – Teva's generic EpiPen – to market. The result of these agreements was to unlawfully extend the exclusivity period, during which the Brand Defendants have monopoly power on epinephrine auto-injectors. The agreement(s) between the Brand Defendants and Teva likely violate federal and state antitrust statutes, as well as state consumer protection laws, because they prevent or delay generic entry, thereby depriving consumers of a less expensive alternative while forcing them to purchase the higher priced branded product.

10. Respondents have kept the Teva Agreement off the publicly available court docket in the Teva Litigation, and deliberately failed to include the Agreement(s) concerning this "blockbuster drug" with Securities & Exchange Commission filings.

B. The Parties To The Petition

11. Petitioner Teamsters Local 404 Health Services and Insurance Plan is headquartered at 115 Progress Ave, Springfield, MA 01104. Teamsters Local 404 is a welfare benefits plan and provides reimbursement for some or all of the purchase price of prescription drugs, including EpiPen. The Teamsters 404 Plan and its members were indirect purchaser of EpiPen and were injured by Respondents' unlawful conduct as alleged herein. The Teamsters 404 Plan sustained injury when it purchased, paid and/or provided reimbursement for EpiPen purchases by its members or their families in Georgia, Massachusetts, New York, Ohio, New Jersey, North Carolina, and Rhode Island.

12. Respondent King Pharmaceuticals, Inc. is headquartered at 501 5th Street, Bristol, TN 37620-2304. King is a vertically integrated pharmaceutical company that performs basic research and develops, manufactures, markets and sells branded prescription pharmaceutical products and animal health products. Its auto-injector business manufactures acute care

medicines for use in humans that are delivered using an auto-injector. In October 2010, King was acquired by Pfizer for $3.6 billion. King is presently a wholly-owned subsidiary of Pfizer.

13. Respondent Meridian Medical Technologies, Inc. is headquartered at 6350 Stevens Forest Road, Suite 301 Columbia, MD 21046. Meridian develops and manufactures specialized products to help emergency medical personnel and military personnel respond to urgent care situations. Meridian offers antidote treatment nerve agent auto-injectors used for the treatment of poisoning by susceptible organophosphorous nerve agents having anticholinesterase activity. King acquired Meridian in 2003, and it went to Pfizer when Pfizer acquired King. Meridian is presently a wholly-owned subsidiary of Pfizer.

14. Respondent Pfizer Inc. is headquartered in New York County at 235 East 42nd Street, New York, NY 10017. Pfizer is a multinational pharmaceutical corporation that develops, manufactures, and sells prescription pharmaceuticals and other healthcare products worldwide. King and Meridian are wholly-owned subsidiaries of Pfizer as a result of Pfizer's acquisition of King.

C. The Relevant CPLR Provision For Pre-Complaint Discovery

CPLR § 3102 (c) provides, in relevant part, as follows:

> **Before action commenced.** Before an action is commenced, disclosure to aid in bringing an action, to preserve information or to aid in arbitration, may be obtained, but only by court order.

D. The Hatch-Waxman Act and Patent Infringement Litigation

15. In 1984, Congress recognized the existence of a health care crisis in this country and attempted to address sky-rocketing prescription drug costs using safe, effective, and less expensive, bioequivalent generic drugs. As such, they passed the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"). Pub. L. No. 98-417, 98 Stat. 1585 (1984).

16. The Hatch-Waxman Act simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need to file lengthy, and costly, New Drug Applications. The ultimate goal of the Hatch-Waxman Act is to "get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C.Cir.), *cert. denied,* 502 U.S. 906, 112 S.Ct. 297, 116 L.Ed.2d 241 (1991). Indeed, "[a]ccording to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[1]

17. The Hatch-Waxman Act accomplishes this by creating a streamlined process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

18. Under the Hatch-Waxman Act, the filing of an ANDA (Paragraph IV certification) gives rise to a cause of action for patent infringement. 35 U.S.C. § 271(e)(2)(A).

19. If the patent owner (branded pharmaceutical company) initiates a patent infringement action against the ANDA filer within 45 days, the FDA may not grant final approval of an ANDA until the earlier of either 30 months or the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). It is well recognized that branded pharmaceutical companies routinely commence patent infringement litigation against generic companies in order to invoke the automatic 30-month stay and improperly perpetuate their monopoly.[2]

20. The patent infringement litigations are commenced by the branded companies because once a generic enters the market, a generic company typically launches its product at

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[1] *See* www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm. Accessed on July 12, 2014.

[2] Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37 (2009); Matther Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 Hastings L.J. 171 (2008-2009); Scott C. Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553 (2006); Julia Rosenthal, *Hatch-Waxman Use or Abuse - Collusive Settlements between Brand-Name and Generic Drug Manufacturers*, 17 Berkeley Tech. L.J. 317 (2002).

40%-60% below the branded price. Moreover, the first generic to market captures approximately 90% of the market share from the branded company within the first six months. Simply put, the branded company loses revenue rapidly and significantly.

21. In addition to filing baseless patent infringement litigations to stave off generic competition, brand name manufacturers have also developed a practice of entering into "reverse payment settlements" in which brand name manufacturers "pay off" generic competitors in exchange for a delay in generic competition. In other words, the branded company agrees to share its monopoly profits with the generic, in exchange for the generic agreeing not to enter the market. This forces consumers and health insurers to purchase the higher priced branded product.

22. Exclusion payment agreements among horizontal competitors not to compete are commonly known as "pay-for-delay" or "reverse payment agreements" – reverse payment because the plaintiff in the litigation atypically pays the defendant to resolve the litigation.

23. Initially, these agreements took the form of a straight cash payment from the brand name manufacturer to the generic competitor. As a result of regulatory scrutiny and Congressional investigations, brand name manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive nature of their agreements. In addition, they deliberately fail to disclose these agreements to the public in company or regulatory filings in order to frustrate potential private investigation by the intended victims of their scheme – consumers and health insurers.

24. Because the profits to be gained by delaying generic competition are so great, brand name drug manufacturers routinely enter into these "reverse payment agreements" in order to secure and retain monopoly profits for as long as possible.

25. In 2013, the United States Supreme Court held that the settlement of a patent infringement suit in which the patentee of a branded pharmaceutical drug gave valuable consideration to a generic to stay out of the market as part of a "reverse payment agreement" could be illegal under the antitrust laws. *FTC v. Actavis, Inc.*, 133 S.Ct. 2223 (2013).

E. The Anticompetitive Patent Settlement Agreement(s)

26. In August 2009, King filed a patent infringement suit against Teva, *King Pharmaceuticals, Inc., et al, v. Teva Parentaeral Medicines, Inc., et al.*, No. 1:09-cv-00652 (N. Del.) alleging infringement of U.S. Patent No. 7,449,012. King filed their First Amended Complaint on November 11, 2010 to include a claim of infringement on U.S. Patent No. 7,794,432.

27. With knowledge that they could not prevail, King and Meridian dropped all claims related to infringement of the '012 patent, leaving only the claims related to the '432 patent.

28. Following discovery, the case against Teva proceeded to a four-day bench trial in March, 2012. The focus of the bench trial was claims 19, 20 and 21 of the '432 patent. According to King and Meridian's counsel, the most important claim terms at issue in the bench trial, all present in claims 19 or 20 of the '432 patent, were "a first locked retracted position," the claim that "energy released from the stored energy source to drive the needle during the medicament dispensing operation is not transferred to the needle cover" and "attenuating kickback."

29. Teva argued that its generic version of the next generation epinephrine auto-injector, as submitted in its application to the FDA, did not infringe the '432 patent for a number of reasons. *First*, Teva's generic equivalent relied on manual insertion of the needle into the

patient, not requiring "a stored energy source capable of driving the plunger within the cartridge to dispense the medicament through the needle assembly." *Second*, Teva's generic equivalent did not have a needle cover that locks in place, as opposed to the '432 patent which requires "the needle cover having a first locked retracted position." *Third*, Teva's generic equivalent did not have energy released from the stored energy source, in direct contradiction to the claims of the '432 patent.

30. In addition to the obvious differences in Teva's auto-injector, as well as favorable claim constructions by the court, the bench trial included evidence of three pieces of "prior art references" which Teva contended invalidated the '432 patent. These references were to Fathallah, Sadowski and Rubin.

31. On the final day of trial, the district court set parameters for post-trial briefing and encouraged the parties to reach an agreement.

32. Respondents announced on April 27, 2012 that they had settled the action, and as a part of the settlement Teva would not begin marketing a generic version of the EpiPen auto-injector until June, 2015 ("Teva Agreement"). As a result of the settlement and regulatory framework of the Hatch-Waxman Act, King and Teva foreclosed entry by any other generic EpiPen auto-injectors from the market until 180 days after Teva's generic release in June, 2015.

33. No rational economic actor with a viable product would refrain from entering a lucrative "blockbuster" market unless they received some form of valuable consideration.

34. Upon information and belief, Teva received unjustifiable consideration, incentives, and benefits in exchange for their collusion in delaying their, and other potential generic EpiPen auto-injectors, from reaching the market before June, 2015 and/or roughly January, 2016 respectively.

35. As a direct and proximate result of these anticompetitive agreement(s) which, violate federal and state antitrust and consumer protection laws, EpiPen purchasers have paid, and will continue to pay, supra-competitive prices.

F. The Request for Immediate Production of the Teva Agreement

36. The Teva Agreement is designed to maintain Respondents' monopoly in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and New York's Donnelly Act, N.Y. Gen. Bus. Law § 340.

37. The Teva Agreement also constitutes a violation of Section 1 of the Sherman Act, 15 U.S.C. §1, and Section 340 of the Donnelly Act,, N.Y. Gen. Bus. Law § 340, as agreements in restraint of trade.

38. Petitioner has established the merits of its cause of action and seeks the Teva Agreement(s) in order to properly frame its complaint, containing both restraint of trade and monopolization claims against Respondents and the generic companies. *FTC. v. Actavis*, 570 U.S. 756 (2013). CPLR § 3102(c) is specifically designed to allow a person to obtain pre-litigation discovery in order to properly and efficiently frame its complaint in precisely this type of situation.[3]

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[3] *In the Matter of Cohen v. Google, Inc.*, 25 Misc.3d 945, 949 (Sup. Ct. 2009) ("[P]etitioner is entitled to pre-action disclosure of information as to the identity of the anonymous blogger, as she had sufficiently established the merits of her proposed cause of action for defamation against that person or persons, and that the information sought is material and necessary to identify the potential defendant or defendants."); *Matter of Wien & Malkin v Wichman*, 255 A.D.2d 244, 680 N.Y.S. 250 (1ST Dep't 1998). (affirming Supreme Court New York County, "The court properly exercised its discretion in directing preaction disclosure pursuant to CPLR 3102 (c) inasmuch as petitioner established that it likely has causes of action against respondent for misappropriation of trade secrets, unfair competition and breach of contract and since the information sought was material and necessary to petitioner's framing of a complaint." (citation omitted); *Hughes v. Witco Corporation—Chempprene Div.*, 175 A.D.2d 486, 487-88, 572 N.Y.S.2D 531, 532 (3d Dep't 1991) (petitioner entitled to conduct pre-trial discovery to "discover the precise facts needed to draft the pleadings."); *Stewart v. New York City Transit Authority*, 112 A.D.2d 939, 940, 292 N.Y.S. 2d 459 (2d Dep't 1985) ("Where, however, the facts alleged state a cause of action . . . examination [pursuant to CPLR § 3102(c)] to determine . . . what form or forms the action should take is appropriate") (citation omitted).

39. No burden will be imposed on Respondents as the requested agreements and related settlement documents are limited in number and readily available.

40. No previous application has been sought for the relief requested herein.

41. Accordingly, Petitioner respectfully requests the agreements and related settlement documents from Respondents pursuant to CPLR § 3102(c).

WHEREFORE, it is reasonably requested that Petitioner be granted an Order permitting it to obtain disclosure pursuant to CPLR § 3102(c), and granting such other order and further relief as the Court may deem just and proper.

Dated: April 30, 2015

By: *Patrick J. Coughlin*

Patrick J. Coughlin