

Generic Drugs – Expanded Complaint October 31, 2017

- Original lawsuit included six defendants and two drugs:

Original Companies:	Original Drugs:
Heritage Pharmaceuticals, Inc.	Doxycycline hyclate delayed release, an antibiotic
Aurobindo Pharma USA, Inc.	Glyburide, an oral diabetes medication.
Citron Pharma, LLC	
Mayne Pharma (USA), Inc.	
Mylan Pharmaceuticals, Inc.	
Teva Pharmaceuticals USA, Inc.	

- The expanded complaint adds 12 new companies and two individuals as defendants, for a total of 20 defendants.

New Companies:	
Actavis Holdco U.S., Inc.	Glenmark Pharmaceuticals, Inc.
Actavis Pharma, Inc.	Lannett Company, Inc.
Ascend Laboratories, LLC	Par Pharmaceutical Companies, Inc.
Apotex Corp.	Sandoz, Inc.
Dr. Reddy's Laboratories, Inc.	Sun Pharmaceutical Industries, Inc.
Emcure Pharmaceuticals, Ltd.	Zydus Pharmacuticals (USA), Inc.

Individual Defendants:	
Rajiv Malik, president and executive director, Mylan N.V., (parent company of Mylan Pharmaceuticals, Inc.)	Satish Mehta, the chief executive officer and managing director, Emcure Pharmaceuticals, Ltd. (parent company of Heritage Pharmaceuticals)

- The expanded complaint adds 13 new drugs, for a total of 15 drugs.

New Drugs:	
Acetazolamide: used to treat glaucoma and epilepsy	Nimodipine: a calcium channel blocking agent used to reduce problems caused by a bleeding blood vessel in the brain
Doxycycline monohydrate: an antibiotic	Nystatin: an antifungal medication
Fosinopril-hydrochlorothiazide: used to treat high blood pressure	Paromomycin: an antibiotic used to treat certain parasite infections
Glipizide-metformin: a diabetes medication	Theophylline: used to treat asthma and other lung problems
Glyburide-metformin: a diabetes medication	Verapamil: used to treat hypertension
Leflunomide: used to treat rheumatoid arthritis	Zoledronic acid: used to treat hypercalcemia
Meprobamate: an anxiety medication	

The Allegations and Ongoing Investigation:

We described the conduct outlined in our initial complaint as "the tip of the iceberg," and stated that our ongoing investigation had revealed much broader collusion across the generic drug market. That initial complaint alleged price fixing by six companies with respect to two drugs.

Today's filing alleges collusion by an additional 12 companies, for a total of 18 defendant companies, as well as 2 individual executives, involving a total of 15 drugs. Alarmingly, we do believe the conduct is even more pervasive, and we continue to investigate with the likelihood of further expansions of the complaint at the appropriate time.

The states allege multiple conspiracies that restrained trade, artificially inflated and/or maintained prices and reduced competition in the generic drug industry. Because generic drug makers don't face the same research and develop costs involved in bringing a branded drug to market, generic drugs should be less expensive and less prone to dramatic price spikes – this is the basic concept behind the federal Hatch-Waxman Act governing generic drug entry into the market.

Generic drug manufacturers argued publicly that significant price increases over the last several years – increases to the tune of prices doubling, tripling and even increasing 1,000 percent or more – were due to benign factors like industry consolidation, FDA-mandated plant closures or elimination of unprofitable generic drug product lines.

The evidence, however, bears out a very different explanation for the failure of generic drugs to fulfill their full cost-savings promises: One where executives and sales personnel at generic drug companies – including some of the highest level executives at certain companies – use their interactions at frequent trade shows, customer conferences and industry dinners, social events and gatherings, as well as phone calls, emails and text messages, to enter into agreements that suppress competition and allocate the market so that everyone gets their share of the market.

Generic drugs are commodities and, therefore, are by and large interchangeable. Thus the only real way for a manufacturer to differentiate their generic from its competitors is price. To avoid competing with each other and avoid price erosion, the companies communicated with each other to determine and agree on how much market share and which customers each company was entitled to. They then implemented the agreement by either refusing to bid for particular customers or by creating an appearance of competition by submitting a "cover bid" – a bid they knew would not be successful so as to ensure another company would be awarded a contract.

The companies also, and in conjunction with the market allocation and price fixing schemes, communicated with each other – either in person, by telephone, text message or other media – and agreed collectively to raise or maintain prices for particular drugs.

Additionally, the evidence demonstrates broad understanding of these conspiracies and agreements across the industry. The evidence also demonstrates that companies understood this conduct was illegal and took steps to both destroy potential evidence and to avoid creating evidence of their actions.

The states allege that this conduct violated both federal and state antitrust laws as well as certain state consumer protection laws.

The litigation thus far has centered on conspiracies in which Heritage Pharmaceuticals served as a central player. The investigation is ongoing as to numerous additional companies, numerous additional drugs and numerous additional conspiracies.

The Customers:

Drug manufacturers typically sell their products through supply agreements negotiated with wholesalers and distributors, group purchasing organizations, pharmacy benefit managers and large retailers, like pharmacy and supermarket chains. Purchasers, such as wholesalers, can buy identical drugs from multiple different generic drug manufacturers – with price being the only point of distinction.

Ideally, purchasers would promote and enforce real competition among generic drug manufacturers in order to restrain drug prices for their own benefit and the benefit of their own downstream customers. However, the complaint details how many customers – including some of the largest distributors in the country – have agreements with the generic manufacturers where they actually benefit when drug prices are higher.

In practice, wholesalers pass the price increases downstream to the end purchaser – federal and state healthcare programs like Medicaid, state employee/retiree health plans, state agencies, employer-funded health plans and consumers. This ability to pass through higher prices reduces incentives to enforce real competition among manufacturers.

Wholesalers, distributors and other customers are not named as defendants in this litigation, and we would decline to comment as to whether any specific entity is under investigation.

That said, the states' investigation involves allegations of conspiracy and collusion within the entirety of the generic drug industry, and wholesalers, distributors and other customers are certainly players within the industry.

The Department of Justice:

As has been widely reported, the DOJ is conducting a criminal investigation into some of the same conduct alleged in the states' complaint. The CT OAG has coordinated with the DOJ during the last 3 ½ years, and early in the investigation provided DOJ with evidence that CT OAG developed in its investigation.

DOJ has recently taken positions on discovery in the multidistrict litigation that would stay discovery for at least another six months. We plan to oppose this effort. While this would prevent the states from engaging in discovery and potentially slow our progress, it would not entirely prevent the states from pursuing evidence related to the broader investigation. We fully intend to do so regardless of the outcome of DOJ's stay motion.

We remain hopeful that we can continue to coordinate with DOJ to accomplish our mutual goals of deterrence and to obtain appropriate relief for past misconduct, but we are fully committed to our case and believe strongly in the importance of the work of the attorneys general on this matter.

We are hopeful that any differences we may have on discovery matters can be resolved amicably through the court process.

The MDL:

Though the case was initially filed in the U.S. District Court for the District of Connecticut, the case was transferred to the Generic Pharmaceuticals Pricing Antitrust multidistrict litigation in Pennsylvania in August 2017.

The transfer was not wholly unexpected and, while we opposed the transfer, we believe that our case is unique and distinct from the class litigation that is also currently in the MDL, and we intend to argue as such going forward.

Suing Individuals:

The complaint names two senior executives:

Rajiv Malik, president and executive director, Mylan N.V., (parent company of Mylan Pharmaceuticals, Inc.)	Satish Mehta, the chief executive officer and managing director, Emcure Pharmaceuticals, Ltd. (parent company of Heritage Pharmaceuticals)
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These two individuals were directly involved in conceiving an illegal agreement and taking affirmative steps to ensure it was executed by their subordinates. Of course, the message they are sending to their employees is one of encouraging illegal conduct.

In this instance, considering the personal conduct of the individuals in furthering the price-fixing scheme, and the brazen and broad nature of the scheme, we believe suing individuals is justified and will send a powerful message deterring this type of conduct. That is why many of the states chose to sue the individual executives as well.

As a general matter, some states have a policy against suing individuals in antitrust cases and leave individuals to be dealt with by the DOJ through the criminal process. As such, some states have not joined in the claims against the two individual defendants.